THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 154995 **Seq:** 1
Reported: 17/07/2000
Hospitalisation:
Onset Date: 22/06/2000
Outcome: Not yet recovered

Gender: M
Weight: 82.00
Age: 56
DOB: 23/07/1943
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flushing		Flushing of the face.	
Rash maculo-papular		Rash on face	

Medicine Details:

REMERON (Suspected) **Reason:** Depression

Oral application 45.0 Milligram Daily Oral

Batch: **Started:** 06/03/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking prinivil, zoton.

Report Detail

Case Number: 165009 **Seq:** 1 **Gender:** F
Reported: 31/05/2001 **Weight:** 77.00
Hospitalisation: **Age:** 45Y
Onset Date: 21/05/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia			

Medicine Details:

MICROLAX ENEMA (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:**
Tablet 2.0 Dose Unspecified As necessary Oral
Batch: **Started:** **Stopped:**

DIAZEPAM (Other drug) **Reason:**
10.0 Milligram As necessary
Batch: **Started:** **Stopped:**

FLUNITRAZEPAM (Other drug) **Reason:**
4.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms 3 hours after dose of mirtazapine. patient recovered 23/5/01. metoclopramide-adverse reaction.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 165009 **Seq:** 1 **Gender:** F
Reported: 31/05/2001 **Weight:** 77.00
Hospitalisation: **Age:** 45Y
Onset Date: 21/05/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

DUROLAX (Other drug)			**Reason:**		
Tablet	4.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
CHLORPROMAZINE HYDROCHLORIDE (Other drug)			**Reason:**		
	50.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
CERUMOL (Other drug)			**Reason:**		
Ear Drops	18.0	Dose Unspecified	Daily		Topical
Batch:	**Started:**	21/05/2001		**Stopped:**	
MIRTAZAPINE (Suspected)			**Reason:**	Depression	
	15.0	Milligram	Daily		
Batch:	**Started:**	21/05/2001		**Stopped:**	22/05/2001

Laboratory Investigations:

Additional Information:

Patient experienced symptoms 3 hours after dose of mirtazapine. patient recovered 23/5/01. metoclopramide-adverse reaction.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 165024 **Seq:** 1 **Gender:** F
Reported: 31/05/2001 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Increased appetite Anorexia Abdominal pain		"binge eating" obsession with eating. Decreased appetite for first 2 weeks.	

Medicine Details:

OROXINE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

MULTIVITAMINS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PANADOL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CELEBREX (Other drug) **Reason:**
0.0
Batch: **Started:** 07/05/2001 **Stopped:** 21/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt ceased celebrex one week ago due to heartburn/discomfort. saw dr last week who confirmed tft's are o'k, say patient is starting menopouse. patient also h as history of ross river virus.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 165024 **Seq:** 1 **Gender:** F
Reported: 31/05/2001 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Medicine Details:

ASPIRIN (Other drug)		**Reason:**	
	0.5 Dose Unspecified Daily		
Batch:	**Started:**		**Stopped:**
REMERON (Suspected)		**Reason:**	Depression
	30.0 Milligram Daily		
Batch:	**Started:** 07/05/2001		**Stopped:**

Laboratory Investigations:

Additional Information:

Pt ceased celebrex one week ago due to heartburn/discomfort. saw dr last week who confirmed tft's are o'k, say patient is starting menopouse. patient also h as history of ross river virus.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 165246 **Seq:** 1
Reported: 08/06/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/06/2001
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 34
DOB: 14/05/1967
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation Tachycardia			Mirtazapine ceased. patient was hosptialised. treated with digoxin and flecainide.

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:** Migraine
1.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

LEVLEN ED (Other drug) **Reason:** Contraception
1.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 22/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prevous atrial flutter associated with nitral value prolapse in 1992. on antiarrythmia for 3 years to 1995. few somptoms subsequently.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 165757 **Seq:** 1
Reported: 26/06/2001
Hospitalisation: Admitted to hospital
Onset Date: 10/06/2001
Outcome: Not yet recovered

Gender: F
Weight: 66.00
Age: 71
DOB: 19/01/1930
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ascites Pleural effusion			Diuretics, fluid restriction. patient hospitalised

Medicine Details:

ASPIRIN (Other drug) **Reason:** Transient cereb isch no hypert
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

MIXTARD 50/50 HUMAN (Other drug) **Reason:** Diabetes mellitus
18.0 Unit Daily
Batch: **Started:** 01/01/2001 **Stopped:**

PANCREASE (Other drug) **Reason:** Acute pancreatitis
Tablet 9.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

REMERON (Suspected) **Reason:**
0.0
Batch: **Started:** 01/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date of remeron is not necessarily accurate but indicates the drug was started sometime in the month. no alcohol abuse. venlafaxine caused rash, losec/omeprazole - neutropenia.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 165757 **Seq:** 1
Reported: 26/06/2001
Hospitalisation: Admitted to hospital
Onset Date: 10/06/2001
Outcome: Not yet recovered

Gender: F
Weight: 66.00
Age: 71
DOB: 19/01/1930
Causality: Causality possible

Reaction Detail

Medicine Details:

MICARDIS (Suspected) **Reason:** Essential benign hypertension
40.0 Milligram Daily
Batch: **Started:** 05/01/2001 **Stopped:**

Laboratory Investigations:

Additional Information:

The dose start date of remeron is not necessarily accurate but indicates the drug was started sometime in the month. no alcohol abuse. venlafaxine caused rash, losec/omeprazole - neutropenia.

Report Detail

Case Number: 166208 **Seq:** 1 **Gender:** F
Reported: 09/07/2001 **Weight:** 64.00
Hospitalisation: **Age:** 80
Onset Date: 15/06/2001 **DOB:** 25/10/1920
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium			Mirtazapince ceased. date of recovery 23.6.01.

Medicine Details:

CELECOXIB (Other drug) **Reason:** Unspecified arthritis
200.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

FERROUS SULPHATE (Other drug) **Reason:**
325.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

OLANZAPINE (Other drug) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mirtazapine commenced at 15mg on 7.6.01, increased to 30mg on 14.6.01. allergy to augmentin duo forte - vomiting, diarrhoea and venlafaxine - decreased na. was already an in-patient.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 166208 **Seq:** 1 **Gender:** F
Reported: 09/07/2001 **Weight:** 64.00
Hospitalisation: **Age:** 80
Onset Date: 15/06/2001 **DOB:** 25/10/1920
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 07/06/2001 **Stopped:** 15/06/2001

Laboratory Investigations:

Additional Information:

Mirtazapine commenced at 15mg on 7.6.01, increased to 30mg on 14.6.01. allergy to augmentin duo forte - vomiting, diarrhoea and venlafaxine - decreased na. was already an in-patient.

Report Detail

Case Number: 166237 **Seq:** 1 **Gender:** F
Reported: 09/07/2001 **Weight:** 60.00
Hospitalisation: **Age:** 45
Onset Date: 03/07/2001 **DOB:** 24/05/1956
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Agitation		Felt like ants crawling over her skin &	Temazepam and lorazepam.

Medicine Details:

ATIVAN (Other drug) **Reason:** Anxiety neurosis
1.0 Milligram As necessary
Batch: **Started:** 03/05/2001 **Stopped:**

TEMAZE (Other drug) **Reason:** Specific disorders of sleep
1.0 Dose Unspecified As necessary
Batch: **Started:** 08/05/2001 **Stopped:**

VOLTAREN EMULGEL (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** 27/02/2001 **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 0.5 Dose Unspecified Total Oral
Batch: **Started:** 03/07/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 167404 **Seq:** 1 **Gender:** F
Reported: 10/08/2001 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 01/08/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Generalised oedema Weight increased		Extensive oedema of abdomen, wrists and Rapid increase in weight.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 30/07/2001 **Stopped:** 06/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 167426 **Seq:** 1 **Gender:** F
Reported: 13/08/2001 **Weight:** 62.00
Hospitalisation: **Age:** 43
Onset Date: 26/07/2001 **DOB:** 21/04/1958
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Could not sleep.	
Hyperkinesia	Severe	Severe akthesia	Given antihistamine. date of recovery 28/07/2001.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 7.5 Milligram Daily Oral

Batch: **Started:** 25/07/2001 **Stopped:** 26/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 167462 **Seq:** 1 **Gender:** F
Reported: 13/08/2001 **Weight:** 82.00
Hospitalisation: **Age:** 61
Onset Date: 02/08/2001 **DOB:** 27/01/1940
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Angry, violent	
Affect lability		Crying	
Agitation			
Anxiety			
Somnolence			Patient required a phone call to a doctor.

Medicine Details:

OESTROGENS NOS (Other drug) **Reason:** Menopausal symptoms
0.0
Batch: **Started:** L TERM **Stopped:** CONTIN

PREMARIN (Other drug) **Reason:** Menopausal symptoms
0.0
Batch: **Started:** L TERM **Stopped:** CONTIN

ASPIRIN (Other drug) **Reason:** Transient cereb isch no hypert
75.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

HYDRENE 25/50 (Other drug) **Reason:** Edema and dropsy
1.0 Dose Unspecified Daily
Batch: **Started:** 01/01/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates that hydrene was started sometime in the month. patient recovered on the 6/8/2001.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 167462 **Seq:** 1 **Gender:** F
Reported: 13/08/2001 **Weight:** 82.00
Hospitalisation: **Age:** 61
Onset Date: 02/08/2001 **DOB:** 27/01/1940
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 01/08/2001 **Stopped:** 02/08/2001

Laboratory Investigations:

Additional Information:

The dose start date is not necessarily accurate but indicates that hydrene was started sometime in the month. patient recovered on the 6/8/2001.

Report Detail

Case Number: 167646 **Seq:** 1
Reported: 15/08/2001
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 45Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension		140/105 then increased to 180/120	Avanza ceased
Nightmare		Nightmares to the point of being afraid to	
Tinnitus		Ringing in both ears	

Medicine Details:

ALDOMET (Other drug) **Reason:** Essential benign hypertension
250.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

OROXINE (Other drug) **Reason:**
100.0 Microgram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 27/07/2001 **Stopped:** 03/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has previously had cipramil, efexor and zoloft without suffering the reaction described.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 167841 **Seq:** 1
Reported: 24/08/2001
Hospitalisation:
Onset Date: 15/08/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 31
DOB: 06/03/1970
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia		Acute dystonic reaction.	
Hyperkinesia		Restlessness.	
Tremor		Shacky feeling.	
Dystonia			Cessation of mirtazepine. required visit to doctor.

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:** Depression
900.0 Milligram Daily
Batch: **Started:** **Stopped:**

VENLAFAXINE HYDROCHLORIDE (Other drug) **Reason:** Depression
300.0 Milligram Daily
Batch: **Started:** 03/07/2001 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 04/08/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 167923 **Seq:** 1 **Gender:** F
Reported: 24/08/2001 **Weight:** 86.00
Hospitalisation: **Age:** 53
Onset Date: 08/08/2001 **DOB:** 26/04/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Itchy rash on abdomen, legs and arms.	Required a visit to doctor. date of recovery: 13/8/2001.

Medicine Details:

Zolpidem Sandoz (Other drug) **Reason:** Specific disorders of sleep
10.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

MIRTAZAPINE (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Erythromycin -> nausea.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 167927 **Seq:** 1 **Gender:** F
Reported: 24/08/2001 **Weight:** 72.00
Hospitalisation: **Age:** 56
Onset Date: 24/07/2001 **DOB:** 05/12/1944
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Osteoarthritis Arthritis Periorbital oedema		Swelling and aching of "all joints".	Required a visit to doctor. mirtazapine withdrawal.

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 19/07/2001 **Stopped:** 24/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 167964 **Seq:** 1 **Gender:** F
Reported: 30/08/2001 **Weight:** 65.00
Hospitalisation: **Age:** 27
Onset Date: 10/08/2001 **DOB:** 10/06/1974
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Marked lower limb akathisia.	Avanza ceased. required a visit to doctor.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 19/06/2001 **Stopped:** 20/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No such side effects with ssri's in the past.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 167998 **Seq:** 1 **Gender:** F
Reported: 31/08/2001 **Weight:** 70.00
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Tinnitus			Persist with medication in the hope it resolves itself.

Medicine Details:

EFEXOR (Other drug) **Reason:** Depression
225.0 Milligram Daily
Batch: **Started:** **Stopped:** 23/08/2001

AVANZA (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 25/08/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 168622 **Seq:** 1
Reported: 22/09/2001
Hospitalisation: Admitted to hospital
Onset Date: 12/09/2001
Outcome: Unknown

Gender: F
Weight:
Age: 37Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain Confusional state Convulsion			Patient hospitalised for 3 days.

Medicine Details:

OXYCODONE HYDROCHLORIDE (Other drug) **Reason:** Pain
0.0
Batch: **Started:** **Stopped:**

BACLOFEN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Oral application 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 168961 **Seq:** 1 **Gender:** F
Reported: 05/10/2001 **Weight:** 100.00
Hospitalisation: **Age:** 46
Onset Date: 23/09/2001 **DOB:** 11/03/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Oedema		Oedematous arms and legs.	
Nervousness		Very irritable.	Avanza ceased.
Arthralgia			
Paraesthesia			

Medicine Details:

EFEXOR-XR (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Oral application 60.0 Milligram Daily Oral
Batch: **Started:** 16/09/2001 **Stopped:** 23/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 169055 **Seq:** 1 **Gender:** U
Reported: 12/10/2001 **Weight:** 80.00
Hospitalisation: **Age:** 38
Onset Date: 06/10/2001 **DOB:** 16/12/1962
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Affect lability		Rage, uncontrolable anger.	Required a visit to doctor. mirtazapine ceased. date of recovery 08/08/01

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 31/07/2001 **Stopped:** 05/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169065 **Seq:** 1 **Gender:** M
Reported: 12/10/2001 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 15/09/2001 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

DIAZEPAM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 15/09/2001

AVANZA (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 28/07/2001 **Stopped:** 15/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 169200 **Seq:** 1 **Gender:** M
Reported: 19/10/2001 **Weight:** 82.00
Hospitalisation: **Age:** 44
Onset Date: 07/10/2001 **DOB:** 28/09/1957
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Sensory loss		Fluctuating paraestesia patchy anaesthesia throughout body	

Medicine Details:

VALIUM (Other drug) **Reason:** Anxiety neurosis
5.0 Milligram Daily
Batch: **Started:** 01/01/2000 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 26/09/2001 **Stopped:** 11/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 17/10/01.

Report Detail

Case Number: 169354 **Seq:** 1 **Gender:** M
Reported: 24/10/2001 **Weight:** 77.00
Hospitalisation: **Age:** 52
Onset Date: 30/05/2001 **DOB:** 03/03/1949
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Treated with clonazepam 1mg bd. date of recovery 3.6.01. mirtazapine ceased.

Medicine Details:

LORAZEPAM (Other drug) **Reason:** Anxiety neurosis
2.5 Milligram As necessary
Batch: **Started:** 30/05/2001 **Stopped:**

THIAMINE (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** 30/05/2001 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 30/05/2001 **Stopped:** 07/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had previously been prescribed other antidepressants which he refused to take due to sexual side-effects.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169449 **Seq:** 1 **Gender:** F
Reported: 26/10/2001 **Weight:** 90.00
Hospitalisation: **Age:** 63
Onset Date: 02/06/2001 **DOB:** 05/04/1938
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Generalised oedema			Required a visit to doctor. date of recovery 12/06/01.

Medicine Details:

NEURONTIN (Other drug) **Reason:** Pain
2.4 Gram Daily
Batch: **Started:** 07/08/2000 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 10/04/2001 **Stopped:** 09/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The oedema recurred on 15mg daily for 2 days.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169467 **Seq:** 1 **Gender:** M
Reported: 29/10/2001 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 10/10/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough		Not from throat, from top of	Date of recovery 15.10.01.

Medicine Details:

VALIUM (Other drug) **Reason:** Specific disorders of sleep
0.5 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

MOGADON (Other drug) **Reason:**
0.5 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

LOSEC (Other drug) **Reason:** Other diseases of esophagus
20.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

JEZIL (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cough appeared within 12 hours of full tablet and disappeared within 12 hours of returning to half tablet.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169467 **Seq:** 1 **Gender:** M
Reported: 29/10/2001 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 10/10/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 10/10/2001 **Stopped:** 14/10/2001

Laboratory Investigations:

Additional Information:

Cough appeared within 12 hours of full tablet and disappeared within 12 hours of returning to half tablet.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169555 **Seq:** 1 **Gender:** M
Reported: 03/10/2001 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: 20/07/2001 **DOB:** 24/10/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation		Life threatening reaction	Patient was hospitalised, echo cardiogram, ecg.
Cardiac valve disease		Tricuspid incompetence	
Pulmonary hypertension			

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Oral application 90.0 Milligram Daily Oral
Batch: **Started:** 15/12/1999 **Stopped:** 20/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169565 **Seq:** 1
Reported: 26/10/2001
Hospitalisation:
Onset Date: 21/09/2001
Outcome: Not yet recovered

Gender: M
Weight: 97.00
Age: 50
DOB: 16/11/1950
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia Generalised oedema Arthralgia	Severe	Aggravation of nocturnal restless legs. Severe generalized oedema.	Treated with feldene.

Medicine Details:

CARDIPRIN 100 (Other drug) **Reason:** Prophylaxis
100.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

NICABATE (Suspected) **Reason:**
Cream 0.0 Transdermal
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169615 **Seq:** 1 **Gender:** F
Reported: 02/11/2001 **Weight:** 55.00
Hospitalisation: **Age:** 60
Onset Date: 10/10/2001 **DOB:** 28/08/1941
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria Osteoarthritis		Itchy rash - widespread	Date of recovery 14/10/01. required a visit to doctor.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
25.0 Milligram Daily
Batch: **Started:** 09/10/2001 **Stopped:** 10/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169812 **Seq:** 1
Reported: 07/11/2001
Hospitalisation:
Onset Date: 05/09/2001
Outcome: Not yet recovered

Gender: F
Weight: 112.00
Age: 39
DOB: 11/06/1962
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Irritable bowel syndrome Myalgia Oedema peripheral			Required a visit to doctor.

Medicine Details:

AVANZA (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169813 **Seq:** 1 **Gender:** M
Reported: 07/11/2001 **Weight:** 72.00
Hospitalisation: **Age:** 78
Onset Date: 13/08/2001 **DOB:** 25/03/1923
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema			Mirtazapine decreased to

Medicine Details:

CAPOTEN (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 26/06/2001 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
500.0 Microgram Daily
Batch: **Started:** 06/08/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 169863 **Seq:** 1
Reported: 09/11/2001
Hospitalisation:
Onset Date: 02/11/2001
Outcome: Not yet recovered

Gender: F
Weight: 76.00
Age: 66
DOB: 14/12/1934
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Oedema of arms and legs.	Required a visit to doctor. mirtazapine ceased.

Medicine Details:

NORVASC (Other drug) **Reason:** Essential benign hypertension
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

PERINDOPRIL (Other drug) **Reason:** Essential benign hypertension
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

DIAZEPAM (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** 20/10/2001 **Stopped:**

KAPANOL (Other drug) **Reason:** Pain
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 169863 **Seq:** 1
Reported: 09/11/2001
Hospitalisation:
Onset Date: 02/11/2001
Outcome: Not yet recovered

Gender: F
Weight: 76.00
Age: 66
DOB: 14/12/1934
Causality: Causality possible

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 01/11/2001 **Stopped:** 06/11/2001

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 170121 **Seq:** 1
Reported: 22/11/2001
Hospitalisation:
Onset Date: 18/11/2001
Outcome: Unknown

Gender: M
Weight: 60.00
Age: 86
DOB: 31/12/1914
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerks.	

Medicine Details:

CEFEPIME HYDROCHLORIDE (Other drug) **Reason:**
2.0 Gram Daily
Batch: **Started:** 10/11/2001 **Stopped:**

VANCOMYCIN HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** 10/11/2001 **Stopped:** 19/11/2001

GENTAMICIN SULPHATE (Suspected) **Reason:**
0.0
Batch: **Started:** 10/11/2001 **Stopped:** 19/11/2001

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 17/11/2001 **Stopped:** 19/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 170121 **Seq:** 1
Reported: 22/11/2001
Hospitalisation:
Onset Date: 18/11/2001
Outcome: Unknown

Gender: M
Weight: 60.00
Age: 86
DOB: 31/12/1914
Causality: Causality possible

Reaction Detail

Medicine Details:

SLOW-K (Suspected) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** 14/11/2001 **Stopped:** 19/11/2001

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 170221 **Seq:** 1 **Gender:** F
Reported: 15/11/2001 **Weight:**
Hospitalisation: **Age:** 75
Onset Date: 28/09/2001 **DOB:** 18/03/1926
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nail disorder		Deep transverse ridging of finger nails.	Required a referral to

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

FOSAMAX (Suspected) **Reason:** Other diseases of bone
70.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

CALCITRIOL (Suspected) **Reason:** Other diseases of bone
0.2 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

THYROXINE SODIUM (Suspected) **Reason:** Myxedema
100.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

Report Detail

Case Number: 170306 **Seq:** 1 **Gender:** M
Reported: 27/11/2001 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: 18/07/2001 **DOB:** 18/09/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice			Required a visit to doctor. date of recovery: 1/8/2001.

Medicine Details:

ZANTAC (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 17/07/2001 **Stopped:** 18/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 170479 **Seq:** 1 **Gender:** M
Reported: 29/11/2001 **Weight:** 80.00
Hospitalisation: **Age:** 54Y
Onset Date: 26/10/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare			Required a visit to doctor. ceased mirtazapine.

Medicine Details:

OXAZEPAM (Other drug) **Reason:**
15.0 Milligram Daily
Batch: **Started:** 16/10/2001 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 24/10/2001 **Stopped:** 06/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The symptoms resolved within in 48 hours of ceasing mirtazapine.

Report Detail

Case Number: 170544 **Seq:** 1 **Gender:** U
Reported: 29/11/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 27/09/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paranoia		Paranoid psychotic beliefs.	Avanza ceased.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug) **Reason:** Otr spec symp psychopathol nec
25.0 Milligram As necessary
Batch: **Started:** 21/09/2001 **Stopped:** CONTIN

FEBRIDOL (Other drug) **Reason:**
500.0 Milligram As necessary
Batch: **Started:** 20/09/2001 **Stopped:** CONTIN

IMOVANE (Other drug) **Reason:** Specific disorders of sleep
15.0 Milligram Daily
Batch: **Started:** 21/09/2001 **Stopped:** 25/09/2001

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 21/09/2001 **Stopped:** 28/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Ect (electroconvulsive therapy) also suspected.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 170957 **Seq:** 1 **Gender:** M
Reported: 10/12/2001 **Weight:** 72.00
Hospitalisation: **Age:** 88Y
Onset Date: 18/09/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Hyperglycaemia			Date of recovery 26.10.01. mirtazapine ceased.

Medicine Details:

PARACETAMOL (Other drug)			**Reason:**		
Oral application	2.0	Dose Unspecified	As necessary	Oral	
Batch:	**Started:**		**Stopped:**		CONTIN
PERICYAZINE (Other drug)			**Reason:**	Unspecified psychosis	
Tablet	5.0	Milligram	Daily	Oral	
Batch:	**Started:**		**Stopped:**		CONTIN
MIRTAZAPINE (Suspected)			**Reason:**		
Oral application	15.0	Milligram	Daily	Oral	
Batch:	**Started:**	07/09/2001	**Stopped:**	04/10/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 171029 **Seq:** 1 **Gender:** F
Reported: 17/12/2001 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 19/11/2001 **DOB:** 16/08/1953
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			Phenergan. required a visit to

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 19/11/2001 **Stopped:** 27/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 171046 **Seq:** 1 **Gender:** F
Reported: 17/12/2001 **Weight:** 55.00
Hospitalisation: **Age:** 65
Onset Date: 11/12/2001 **DOB:** 29/05/1936
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dizziness Hypoaesthesia Stridor			Date of recovery 11.12.01. mirtazapine ceased. patient was already in hospital.

Medicine Details:

SIMVASTATIN (Other drug) **Reason:** Othr&unspec metabolic diseases
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

RANITIDINE (Other drug) **Reason:** Other diseases of esophagus
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

METOCLOPRAMIDE HYDROCHLORIDE (Other drug) **Reason:** Nausea and vomiting
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 171046 **Seq:** 1
Reported: 17/12/2001
Hospitalisation:
Onset Date: 11/12/2001
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 65
DOB: 29/05/1936
Causality: Causality possible

Reaction Detail

Medicine Details:

CITALOPRAM HYDROBROMIDE (Suspected)		**Reason:** Depression	
	10.0 Milligram	Daily	
Batch:	**Started:** 04/12/2001		**Stopped:** 11/12/2001
MIRTAZAPINE (Suspected)		**Reason:** Depression	
	15.0 Milligram	Daily	
Batch:	**Started:** 11/12/2001		**Stopped:** 11/12/2001

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 171093 **Seq:** 1 **Gender:** F
Reported: 12/12/2001 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 15/10/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular disorder			Clopidogrel

Medicine Details:

REMERON (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 15/09/2001 **Stopped:** 15/10/2001 1M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 171380 **Seq:** 1
Reported: 20/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 02/12/2001
Outcome: Recovered

Gender: F
Weight: 80.00
Age: 43
DOB: 07/01/1958
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Asthenia Coordination abnormal Coordination abnormal Muscle twitching		Tingling in arms/hands. Weak legs/dragging.	Patient hospitalised.

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 02/12/2001

AVANZA (Interaction) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** **Stopped:** 03/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction improved when dose of avanza decreased, worsened when dose increased.

Report Detail

Case Number: 171405 **Seq:** 1 **Gender:** M
Reported: 20/12/2001 **Weight:** 121.00
Hospitalisation: **Age:** 58Y
Onset Date: 09/12/2001 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Severe	Body tremor.	
Photopsia		Flashing blue lights in vision.	
Somnolence		Severe sedation.	
Dry mouth			
Hyperkinesia			

Medicine Details:

FELDENE (Other drug) **Reason:** Osteoarthritis
0.0
Batch: **Started:** L TERM **Stopped:**

VENLAFAXINE HYDROCHLORIDE (Other drug) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** 20/11/2001 **Stopped:** 12/12/2001

XENICAL (Other drug) **Reason:** Depression
3.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

MICARDIS (Other drug) **Reason:** Essential benign hypertension
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mirtazapine was rechallenged causing the same reaction to occur. mirtazapine was also taken at 7.5mg. patient also taking osteoese.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 171405 **Seq:** 1 **Gender:** M
Reported: 20/12/2001 **Weight:** 121.00
Hospitalisation: **Age:** 58Y
Onset Date: 09/12/2001 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Mirtazapine was rechallenged causing the same reaction to occur. mirtazapine was also taken at 7.5mg. patient also taking osteoese.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 171465 **Seq:** 1 **Gender:** F
Reported: 02/01/2002 **Weight:** 74.00
Hospitalisation: **Age:** 40Y
Onset Date: 14/12/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous Face oedema Periorbital oedema		Blotchy rash over chest and arms	Mirtazapine ceased. diprosone oin, hydraderm. date of recovery 28/12/01.

Medicine Details:

NALTREXONE HYDROCHLORIDE (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

MYADEC (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

ALDACTONE (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

LACTULOSE (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 171465 **Seq:** 1 **Gender:** F
Reported: 02/01/2002 **Weight:** 74.00
Hospitalisation: **Age:** 40Y
Onset Date: 14/12/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 13/12/2001 **Stopped:** 20/12/2001

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 171560 **Seq:** 1
Reported: 07/01/2002
Hospitalisation:
Onset Date: 21/12/2001
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 82
DOB: 15/09/1919
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			Ceased mirtazapine.

Medicine Details:

CAPTOPRIL (Other drug) **Reason:** Essential benign hypertension
25.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

PROPOFOL (Other drug) **Reason:** Essential benign hypertension
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

TEMAZEPAM (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

MIXTARD 30/70 (Other drug) **Reason:** Diabetes mellitus
20.0 Unit Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	ALT = SGPT		17/07/2003	182	
17/12/2002	ALT = SGPT		17/07/2003	30	
17/12/2002	AST = SGOT		17/07/2003	91	
17/12/2002	AST = SGOT		17/07/2003	32	
17/12/2002	GGT = SGGT =		17/07/2003	358	
17/12/2002	GGT = SGGT =		17/07/2003	235	
17/12/2002	LDH		17/07/2003	214	

Additional Information:

Report Detail

Case Number: 171560 **Seq:** 1
Reported: 07/01/2002
Hospitalisation:
Onset Date: 21/12/2001
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 82
DOB: 15/09/1919
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 28/11/2001 **Stopped:** 23/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	LDH		17/07/2003	164	
17/12/2002	SAP = ALP		17/07/2003	326	
17/12/2002	SAP = ALP		17/07/2003	174	

Additional Information:

Report Detail

Case Number: 171950 **Seq:** 1 **Gender:** F
Reported: 16/01/2002 **Weight:** 60.00
Hospitalisation: **Age:** 18
Onset Date: 10/01/2002 **DOB:** 19/09/1983
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Severe dizziness	Avanza ceased. required a visit to doctor. date of recovery 13/01/02

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 09/01/2002 **Stopped:** 11/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient abusus mersyndol - likes its sadative effects.

Report Detail

Case Number: 172017 **Seq:** 1
Reported: 21/01/2002
Hospitalisation:
Onset Date: 28/10/2001
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 48
DOB: 18/04/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

OXAZEPAM (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:** CONTIN

MOGADON (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:** CONTIN

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 01/07/2001 **Stopped:** 28/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start and stop date for the drug mirtazapine is not necessarily accurate but indicates the drug was started and stopped sometime in the month. the date of onset is not accurate but indicates onset sometime in the year.

Report Detail

Case Number: 172253 **Seq:** 1 **Gender:** M
Reported: 29/01/2002 **Weight:** 75.00
Hospitalisation: **Age:** 66
Onset Date: 01/01/2002 **DOB:** 10/09/1935
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nervousness Thinking abnormal Constipation		Extreme irritability. Lack of concentration and motivation.	Required a visit to doctor.

Medicine Details:

VALIUM (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

AURORIX (Other drug) **Reason:**
750.0 Milligram Daily
Batch: **Started:** **Stopped:**

TEMAZE (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
0.0
Batch: **Started:** 20/12/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 172257 **Seq:** 1
Reported: 29/01/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia Paraesthesia Muscular weakness Paraesthesia		Extreme aches and pains in legs and arms. Lips tingling.	Patient was hospitalised.

Medicine Details:

XANAX (Suspected) **Reason:** Anxiety neurosis
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 172279 **Seq:** 1 **Gender:** F
Reported: 31/01/2002 **Weight:** 134.00
Hospitalisation: **Age:** 57
Onset Date: 24/12/2001 **DOB:** 24/10/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthritis		Acute polyarthritis esp large joints.	Withdrawal of mirtazapine. required a visit to doctor.

Medicine Details:

NAPROXEN (Other drug) **Reason:**
Suppository 1.0 Dose Unspecified As necessary Rectal
Batch: **Started:** **Stopped:**

ASMOL (Other drug) **Reason:**
Inhalation 100.0 Microgram As necessary Inhalation
Batch: **Started:** **Stopped:**

ZOLOFT (Other drug) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TEARS NATURALE (Other drug) **Reason:**
Eye Drops 8.0 Dose Unspecified Daily Ophthalmic
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking solprin, nitrolingual pumpspray, pulmicort, imdur lipitor, vasocardol, aldartone, lasix, febridol, pamadeine forte, allopurinol, glyade. allergies, penicillin oedema, phenothiazines -mania, flagyl-diarrhoea, rondomycin-rash, di-gesic, ergotamine, erythromycin, benzodiazepines, naprosyn, tomatoes.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 172279 **Seq:** 1 **Gender:** F
Reported: 31/01/2002 **Weight:** 134.00
Hospitalisation: **Age:** 57
Onset Date: 24/12/2001 **DOB:** 24/10/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

DIAFORMIN (Other drug)			**Reason:**		
Tablet	2.0	Gram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
AVANZA (Suspected)			**Reason:**	Depression	
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**	10/12/2001		**Stopped:**	21/01/2002

Laboratory Investigations:

Additional Information:

Patient was also taking solprin, nitrolingual pumpspray, pulmicort, imdur lipitor, vasocardol, aldartone, lasix, febridol, pamadeine forte, allopurinol, glyade. allergies, penicillin oedema, phenothiazines -mania, flagyl-diarrhoea, rondomycin-rash, di-gesic, ergotamine, erythromycin, benzodiazepines, naprosyn, tomatoes.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 172314 **Seq:** 1 **Gender:** F
Reported: 31/01/2002 **Weight:** 52.00
Hospitalisation: **Age:** 81Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Dizziness Fatigue Hepatitis cholestatic			

Medicine Details:

DIDROCAL (Other drug) **Reason:** Other diseases of bone
0.0
Batch: **Started:** **Stopped:**

COVERSYL (Other drug) **Reason:** Essential benign hypertension
4.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
15.0 Milligram Fortnightly
Batch: **Started:** 26/12/2001 **Stopped:** 25/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/01/2002	ALT = SGPT				Alt 121.
31/01/2002	AST = SGOT				Ast 58.
31/01/2002	GGT = SGGT =				Ggt 686.
31/01/2002	SAP = ALP				Alp 482

Additional Information:

The dose of onset is not necessarily accurate but indicates onset sometime in the month. allergy: amoxycillin - rah.

Report Detail

Case Number: 172330 **Seq:** 1
Reported: 01/02/2002
Hospitalisation:
Onset Date: 13/01/2002
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 46
DOB: 03/11/1955
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Rash on trunk, back, upper tighs, arms.	Phenergan. required a visit to

Medicine Details:

ANTENEX (Other drug) **Reason:**
2.5 Milligram As necessary
Batch: **Started:** **Stopped:**

TEGRETOL (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** L TERM **Stopped:**

CIPRAMIL (Other drug) **Reason:** Depression
80.0 Milligram Daily
Batch: **Started:** **Stopped:**

VIOXX (Other drug) **Reason:** Unspecified arthritis
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Probable glossitis and cheilitis from carbamazepine.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 172330 **Seq:** 1
Reported: 01/02/2002
Hospitalisation:
Onset Date: 13/01/2002
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 46
DOB: 03/11/1955
Causality: Causality possible

Reaction Detail

Medicine Details:

FEFOL (Other drug)			**Reason:**	
	1.0	Dose Unspecified	Daily	
Batch:	**Started:**	L TERM	**Stopped:**	
AVANZA (Suspected)			**Reason:**	Depression
	30.0	Milligram	Daily	
Batch:	**Started:**	10/01/2002	**Stopped:**	13/01/2002

Laboratory Investigations:

Additional Information:

Probable glossitis and cheilitis from carbamazepine.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 172367 **Seq:** 1 **Gender:** F
Reported: 04/02/2002 **Weight:** 85.00
Hospitalisation: **Age:** 48
Onset Date: 28/01/2002 **DOB:** 12/02/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diplopia Nervousness Pain			Required a visit to doctor.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 172546 **Seq:** 1 **Gender:** F
Reported: 11/02/2002 **Weight:** 60.00
Hospitalisation: **Age:** 39Y
Onset Date: 22/01/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Excessive sedation	

Medicine Details:

ORAL CONTRACEPTIVE NOS (Other drug) **Reason:** Contraception
0.0
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 22/01/2002 **Stopped:** 26/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 172570 **Seq:** 1 **Gender:** M
Reported: 11/02/2002 **Weight:** 95.00
Hospitalisation: **Age:** 44Y
Onset Date: 24/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Excessive sedation	Ceased mirtazapine

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
15.0 Milligram 1 time
Batch: **Started:** 24/08/2001 **Stopped:** 25/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pateint took a single dose of mirtazapine 15mg on evening of 24/8/01. noted significant drowsiness after sleeping 12 hours.

Report Detail

Case Number: 172801 **Seq:** 1 **Gender:** M
Reported: 15/02/2002 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 22/01/2002 **DOB:** 25/08/1951
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Substantial oedema to lower limbs/girth.	

Medicine Details:

NEURONTIN (Other drug) **Reason:** Pain
800.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

DOLOXENE (Other drug) **Reason:** Pain
2.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

PANADEINE FORTE (Other drug) **Reason:** Pain
6.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

DEXAMPHETAMINE SULPHATE (Other drug) **Reason:**
15.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 30/1/02.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 172801 **Seq:** 1 **Gender:** M
Reported: 15/02/2002 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 22/01/2002 **DOB:** 25/08/1951
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
45.0 Milligram Daily
Batch: **Started:** 15/01/2002 **Stopped:** 22/01/2002

Laboratory Investigations:

Additional Information:

Patient recovered 30/1/02.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 172870 **Seq:** 1
Reported: 18/02/2002
Hospitalisation:
Onset Date: 07/02/2002
Outcome: Not yet recovered

Gender: M
Weight: 79.00
Age: 52
DOB: 10/05/1949
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Flatulence Weight increased	Severe	Severe headache.	Required a visit to docotor.

Medicine Details:

AVANZA (Suspected) **Reason:**

1.0 Dose Unspecified Daily

Batch: **Started:** 04/02/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 172992 **Seq:** 1
Reported: 20/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/01/2002
Outcome: Recovered

Gender: M
Weight: 90.00
Age: 78
DOB: 06/01/1924
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium Hyponatraemia	Severe	Acute and severe delerium.	Date of recovery 18.2.02. patient was hospitalised. avanza and campral ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
45.0 Milligram Daily
Batch: **Started:** 15/01/2002 **Stopped:** 03/02/2002

CAMPRAL (Suspected) **Reason:** Alcoholism
333.0 Milligram Daily
Batch: **Started:** **Stopped:** 03/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173036 **Seq:** 1
Reported: 22/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/01/2002
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 43
DOB: 20/10/1958
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:** Other&unspecified epilepsy
2.0 Gram Daily
Batch: **Started:** L TERM **Stopped:**

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 22/01/2002 **Stopped:** 31/01/2002

CLONAZEPAM (Suspected) **Reason:** Anxiety neurosis
3.0 Milligram Daily
Batch: **Started:** 17/01/2001 **Stopped:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
100.0 Milligram Daily
Batch: **Started:** 17/01/2002 **Stopped:** 31/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Platelets		01/05/2006	84	

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173139 **Seq:** 1 **Gender:** M
Reported: 26/02/2002 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 04/01/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 20/12/2001 **Stopped:** 04/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 173213 **Seq:** 1 **Gender:** F
Reported: 28/02/2002 **Weight:** 56.00
Hospitalisation: **Age:** 54
Onset Date: 31/01/2002 **DOB:** 21/07/1947
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urine analysis abnormal		Dark urine.	
Agitation			
Diarrhoea			
Glossitis			
Headache			Date of recovery 05/02/2002. required a visit to doctor.
Hyperhidrosis			
Nausea			
Thirst			

Medicine Details:

PRAVACHOL (Other drug) **Reason:** Othr&unspec metabolic diseases
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AVANZA (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173349 **Seq:** 1 **Gender:** F
Reported: 04/03/2002 **Weight:** 85.00
Hospitalisation: **Age:** 27
Onset Date: 23/01/2002 **DOB:** 27/01/1974
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Loss of bladder control.	
Faecal incontinence		Loss of bowel control.	
Convulsion		Muscular spasms to upper body.	Date of recovery 27.1.02. required a visit to doctor.

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis
15.0 Milligram Daily
Batch: **Started:** 21/01/2002 **Stopped:** 25/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient developed side effects to other classes of antidepressants.

Report Detail

Case Number: 173350 **Seq:** 1
Reported: 04/03/2002
Hospitalisation:
Onset Date: 24/09/2001
Outcome: Not yet recovered

Gender: F
Weight: 66.00
Age: 73Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Restless legs.	Mirtazepine ceased.

Medicine Details:

BENDROFLUAZIDE (Other drug) **Reason:** Essential benign hypertension
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

AMIODARONE HYDROCHLORIDE (Other drug) **Reason:** Otr&nos disord of heart rhythm
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

OMEPRAZOLE (Other drug) **Reason:** Gastritis&duodenitis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PANTOPRAZOLE (Other drug) **Reason:** Gastritis&duodenitis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Occurred on previous treatment of this drug - 1/12 ago. reaction stopped on cessation of drug and recommenced on restarting it.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173350 **Seq:** 1
Reported: 04/03/2002
Hospitalisation:
Onset Date: 24/09/2001
Outcome: Not yet recovered

Gender: F
Weight: 66.00
Age: 73Y
DOB:
Causality: Causality certain

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 24/09/2001 **Stopped:**

Laboratory Investigations:

Additional Information:

Occurred on previous treatment of this drug - 1/12 ago. reaction stopped on cessation of drug and recommenced on restarting it.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173499 **Seq:** 1 **Gender:** M
Reported: 08/03/2002 **Weight:** 130.00
Hospitalisation: **Age:** 49
Onset Date: 18/12/2001 **DOB:** 19/12/1951
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Acute episode of	Avanza discontinued. date of recovery 20/12/2001. required a visit to doctor.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 12/12/2001 **Stopped:** 19/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past history - long history of major depression.

Report Detail

Case Number: 173790 **Seq:** 1
Reported: 21/03/2002
Hospitalisation:
Onset Date: 19/02/2002
Outcome: Not yet recovered

Gender: F
Weight: 75.00
Age: 44
DOB: 06/09/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Increased appetite Weight increased Diarrhoea Faecal incontinence Flatulence		Food craving Weight gain 3 kg.	Imodium, required a visit to

Medicine Details:

CHLORPROPAMIDE (Other drug) **Reason:** Specific disorders of sleep
25.0 Milligram As necessary
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 01/02/2002 **Stopped:** 04/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173801 **Seq:** 1
Reported: 22/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/02/2002
Outcome: Not yet recovered

Gender: F
Weight: 74.00
Age: 79
DOB: 23/03/1922
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anaemia Dyspnoea Neutropenia Palpitations			Admitted to hospital.

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:**
200.0 Microgram Daily
Batch: **Started:** **Stopped:** CONTIN

BUMETANIDE (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** **Stopped:** 18/02/2002

SLOW-K (Other drug) **Reason:**
1.2 Gram Daily
Batch: **Started:** **Stopped:** CONTIN

DILTIAZEM HYDROCHLORIDE (Other drug) **Reason:**
180.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils	(2.0-7.5)	14/02/2002	1.08	
	Neutrophils	(2.0-7.5)	18/02/2002	0.72	
	Neutrophils	(2.0-7.5)	19/02/2002	0.76	
	Neutrophils	(2.0-7.5)	28/02/2002	0.77	
	Neutrophils	(2.0-7.5)	06/03/2002	0.89	
	Neutrophils	(2.0-7.5)	04/03/2002	0.84	
	Neutrophils	(2.0-7.5)	25/02/2002	1.14	

Additional Information:

The dose start date for the drug mirtazapine is not accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173801 **Seq:** 1
Reported: 22/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/02/2002
Outcome: Not yet recovered

Gender: F
Weight: 74.00
Age: 79
DOB: 23/03/1922
Causality: Causality possible

Reaction Detail

Medicine Details:

SEREPAX (Other drug)			**Reason:**	
	45.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
RANITIDINE (Other drug)			**Reason:**	
	300.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
MIRTAZAPINE (Suspected)			**Reason:**	
	15.0 Milligram	Daily		
Batch:	**Started:** 01/10/2001		**Stopped:**	18/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	(4.0-11.0)	14/02/2002	2.2	
	White blood cells	(4.0-11.0)	18/02/2002	1.8	
	White blood cells	(4.0-11.0)	19/02/2002	1.8	
	White blood cells	(4.0-11.0)	25/02/2002	2.2	
	White blood cells	(4.0-11.0)	28/02/2002	1.7	
	White blood cells	(4.0-11.0)	04/03/2002	2.0	
	White blood cells	(4.0-11.0)	06/03/2002	1.9	

Additional Information:

The dose start date for the drug mirtazapine is not accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173881 **Seq:** 1
Reported: 25/03/2002
Hospitalisation:
Onset Date: 17/01/2002
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 60
DOB: 01/09/1941
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain Breast engorgement		Swollen painfull breast persisting 2 weeks	Required a visit to doctor. brufen and vitamin b6.

Medicine Details:

MENOREST (Other drug) **Reason:**
1.0 Dose Unspecified Weekly
Batch: **Started:** **Stopped:**

HALCION (Other drug) **Reason:** Specific disorders of sleep
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 08/01/2002 **Stopped:** 27/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 173902 **Seq:** 1 **Gender:** M
Reported: 25/03/2002 **Weight:** 93.00
Hospitalisation: **Age:** 52Y
Onset Date: 12/03/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Osteoarthritis Oedema peripheral Osteoarthritis		Bilateral effusions knees (painless).	Ceased avanza. 3/7 lasix.

Medicine Details:

SERETIDE ACCUHALER NOS (Other drug) **Reason:** Asthma
Inhalation 2.0 Dose Unspecified Daily Inhalation
Batch: **Started:** 31/01/2002 **Stopped:** CONTIN

AVAPRO (Other drug) **Reason:** Essential benign hypertension
300.0 Milligram Daily
Batch: **Started:** 31/01/2002 **Stopped:** CONTIN

CELEBREX (Other drug) **Reason:** Osteoarthritis
200.0 Milligram Daily
Batch: **Started:** 19/09/2001 **Stopped:** CONTIN

AVANZA (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 26/02/2002 **Stopped:** 13/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 173972 **Seq:** 1 **Gender:** F
Reported: 19/03/2002 **Weight:** 60.00
Hospitalisation: **Age:** 42
Onset Date: 01/03/2002 **DOB:** 23/05/1959
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Interupted sleep, jumped out from sleep.	Required a visit by doctor. date of recovery: 13/3/2002.

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

AVANZA (Interaction) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 27/02/2002 **Stopped:** 08/03/2002

CAPADEX (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** 01/02/2002 **Stopped:** CONTIN

PREMARIN (Other drug) **Reason:**
625.0 Microgram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173972 **Seq:** 1
Reported: 19/03/2002
Hospitalisation:
Onset Date: 01/03/2002
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 42
DOB: 23/05/1959
Causality: Causality possible

Reaction Detail

Medicine Details:

URAL (Other drug)		**Reason:**		
	3.0 Dose Unspecified	Daily		
Batch:	**Started:** 01/02/2002		**Stopped:**	CONTIN
ATIVAN (Other drug)		**Reason:**		
	4.5 Milligram	Daily		
Batch:	**Started:** 25/02/2002		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 173999 **Seq:** 1 **Gender:** M
Reported: 27/03/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 19/03/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eaton-Lambert syndrome		Acute deterioration in myasthenia gravis	Recovered in 24 hours. required a call to doctor.

Medicine Details:

PREDNISONE (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

AZATHIOPRINE (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

KAPANOL (Other drug) **Reason:**
0.0
Batch: **Started:** S TERM **Stopped:**

PYRIDOSTIGMINE BROMIDE (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has depression secondary to metastatic ca. lung.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 173999 **Seq:** 1 **Gender:** M
Reported: 27/03/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 19/03/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Patient has depression secondary to metastatic ca. lung.

Report Detail

Case Number: 174000 **Seq:** 1
Reported: 27/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2002
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 60
DOB: 04/06/1941
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oculogyration Agitation Anorexia Coma Confusional state Malaise Renal failure acute Sepsis Syncope		Abnormal eye movements	Admitted to icu, initiated on

Medicine Details:

QUETIAPINE (Suspected) **Reason:** Depression
600.0 Milligram Daily
Batch: **Started:** **Stopped:** 04/03/2002

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 28/02/2002 **Stopped:** 04/03/2002

DIAMICRON (Suspected) **Reason:** Diabetes mellitus
320.0 Milligram Daily
Batch: **Started:** **Stopped:** 04/03/2002

DIABEX (Suspected) **Reason:** Diabetes mellitus
1.7 Gram Daily
Batch: **Started:** **Stopped:** 04/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine		06/03/2002	616	
	Creatinine		12/03/2002	323	
	Creatinine		11/03/2002	235	

Additional Information:

Report Detail

Case Number: 174228 **Seq:** 1 **Gender:** M
Reported: 05/04/2002 **Weight:** 100.00
Hospitalisation: **Age:** 59
Onset Date: 05/02/2002 **DOB:** 25/06/1942
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Ankles and feet travelling up to knees.	Required a visit to doctor. date of recovery: 5/3/2002.

Medicine Details:

AROPAX (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** 20/01/2002

VALPRO (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:** CONTIN

AVANZA (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 23/01/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Avanza commenced on 21/1 at 15mg for 2 days.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 174262 **Seq:** 1 **Gender:** F
Reported: 08/04/2002 **Weight:** 70.00
Hospitalisation: **Age:** 80
Onset Date: 12/06/2001 **DOB:** 25/10/1920
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium			

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 07/06/2001 **Stopped:** 15/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 174464 **Seq:** 1
Reported: 12/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 01/02/2002
Outcome: Recovered

Gender: M
Weight:
Age: 55
DOB: 18/07/1946
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Hyperkinesia Nervousness			Patient hospitalised.

Medicine Details:

OXYCONTIN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** 21/02/2002

CELEBREX (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** 21/02/2002

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 21/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 174625 **Seq:** 1 **Gender:** F
Reported: 18/04/2002 **Weight:** 48.00
Hospitalisation: **Age:** 29
Onset Date: 16/02/2002 **DOB:** 27/02/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral Rash maculo-papular		Peripheral non-pitting oedema.	Required a visit to doctor. date of recovery; 22/2/2002.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 11/02/2002 **Stopped:** 18/02/2002

BUPRENORPHINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Sublingual
Batch: **Started:** 08/02/2002 **Stopped:**

DIAZEPAM (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 07/02/2000 **Stopped:** 08/02/2002

MULTI-B FORTE (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 07/02/2002 **Stopped:** 18/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 174625 **Seq:** 1
Reported: 18/04/2002
Hospitalisation:
Onset Date: 16/02/2002
Outcome: Recovered

Gender: F
Weight: 48.00
Age: 29
DOB: 27/02/1972
Causality: Causality possible

Reaction Detail

Medicine Details:

MULTIVITAMINS (Suspected) **Reason:**

Oral application 1.0 Dose Unspecified Daily Oral

Batch: **Started:** 07/02/2002 **Stopped:** 18/02/2002

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 174846 **Seq:** 1 **Gender:** U
Reported: 26/04/2002 **Weight:** 95.00
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 09/11/1951
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Headache Increased appetite Oedema Rash Weight increased			Mirtazapine ceased.

Medicine Details:

PANTOPRAZOLE (Other drug) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ALLOPURINOL (Other drug) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

VIOXX (Other drug) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TRANDOLAPRIL (Other drug) **Reason:**
Capsule 1.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 174846 **Seq:** 1
Reported: 26/04/2002
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: U
Weight: 95.00
Age: 50
DOB: 09/11/1951
Causality: Causality probable

Reaction Detail

Medicine Details:

PRAVASTATIN SODIUM (Other drug)			**Reason:**		
Tablet	40.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**		
Tablet	4.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
MIRTAZAPINE (Suspected)			**Reason:**	Depression	
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**	30/03/2002		**Stopped:**	08/04/2002

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 175113 **Seq:** 1 **Gender:** F
Reported: 06/05/2002 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: 23/02/2002 **DOB:** 07/01/1979
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Anxiety Weight increased			Mirtazepine ceased.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 24/01/2002 **Stopped:** 23/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history - depression, post natal depression since 6/01, iv amphetamine user(says > 12 months ago), cannabis user(current).

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 175114 **Seq:** 1
Reported: 06/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 23/02/2002
Outcome: Recovered

Gender: F
Weight:
Age: 23
DOB: 07/01/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Aggression Agitation Grand mal convulsion Hallucination Paranoia		Total of 20 grand male seizers.	Treated with diazepam 40mg and phenytoin 1.5g. presented to hospital

Medicine Details:

MIRTAZAPINE (Interaction) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 24/01/2002 **Stopped:** 23/02/2002

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 23/02/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history - depression, post natal depression since 06/01, iv amphetamine user (says > 12 months ago), cannabis user (current).

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 175191 **Seq:** 1
Reported: 03/05/2002
Hospitalisation:
Onset Date: 28/01/2002
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 33
DOB: 06/06/1968
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug dependence		Increased tobacco craving and smoking.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
45.0 Milligram Daily
Batch: **Started:** 17/12/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. ssri, swri, tca, rima and nefazadone - all tried in past with no increased tabacco craving.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 175226 **Seq:** 1 **Gender:** F
Reported: 07/05/2002 **Weight:**
Hospitalisation: **Age:** 85Y
Onset Date: 01/01/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema		Generalised oedema.	Mirtazapine ceased prior to admission. metformin, warfarin and lorazepam started on admission

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug) **Reason:**
Tablet 1.0 Gram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

WARFARIN SODIUM (Other drug) **Reason:**
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 13/02/2002

LORAZEPAM (Other drug) **Reason:**
Tablet 0.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

MIRTAZAPINE (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 03/11/2001 **Stopped:** 28/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose stop date for mirtazapine is not necessarily accurate but indicates the drug was stopped sometime in the month.

Report Detail

Case Number: 175317 **Seq:** 1
Reported: 19/03/2002
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 47.00
Age: 54
DOB: 25/08/1947
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			

Medicine Details:

EPILIM (Suspected) **Reason:** Depression
600.0 Milligram Daily
Batch: **Started:** 17/01/2002 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
90.0 Milligram Daily
Batch: **Started:** 05/07/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets		29/01/2002	159000	
	Platelets		05/02/2002	148000	
	Platelets		01/03/2002	130000	

Additional Information:

According to the doctor, sodium valproate is just in therapeutic range.

Report Detail

Case Number: 175483 **Seq:** 1 **Gender:** M
Reported: 10/05/2002 **Weight:** 100.00
Hospitalisation: **Age:** 37
Onset Date: 17/04/2002 **DOB:** 27/05/1964
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Insomnia Somnolence		In lala land/out of it. Insomnia walking up all night.	Required a visit to doctor.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** 16/04/2002 **Stopped:** 23/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 24/4/02.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 175495 **Seq:** 1 **Gender:** M
Reported: 15/05/2002 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: 06/05/2002 **DOB:** 11/12/1949
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare Confusional state Dizziness Somnolence	Severe	Severe nightmares	

Medicine Details:

AVANZA (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 11/5/02.

Report Detail

Case Number: 175612 **Seq:** 1 **Gender:** F
Reported: 21/05/2002 **Weight:**
Hospitalisation: **Age:** 66
Onset Date: 19/11/2001 **DOB:** 04/07/1935
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

ATIVAN (Other drug) **Reason:**
0.0
Batch: **Started:** 01/01/1975 **Stopped:**

STILNOX (Other drug) **Reason:**
0.0
Batch: **Started:** 06/08/2001 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 08/10/2001 **Stopped:** 05/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		19/01/2001	1.9	
	Neutrophils		04/12/2001	1.5	
	Neutrophils		14/01/2002	2.0	

Additional Information:

Suspected drug positive rechallenge. remeron was discontinued after a treatment period of 2 months and the neutrophil level restored. remeron was reintroduced 3 months later and the patient again developed neutropenia after 1 week of treatment.

Report Detail

Case Number: 175613 **Seq:** 1 **Gender:** F
Reported: 21/05/2002 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: 20/04/2002 **DOB:** 31/07/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 90.0 Milligram Daily Oral

Batch: **Started:** 16/01/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				Neutro 1.4, normal 2.0-7.5. another week later neutro's 4.1.

Additional Information:

Report Detail

Case Number: 175621 **Seq:** 1 **Gender:** M
Reported: 22/05/2002 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 25/04/2002 **DOB:** 18/08/1924
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		On trunk, hands and knees.	

Medicine Details:

IRBESARTAN (Other drug) **Reason:** Essential benign hypertension
75.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZYLOPRIM (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** **Stopped:**

LOSEC (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

VALIUM (Other drug) **Reason:**
2.5 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 175621 **Seq:** 1 **Gender:** M
Reported: 22/05/2002 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 25/04/2002 **DOB:** 18/08/1924
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

DINDEVAN (Other drug)			**Reason:**	
	40.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	
AVANZA (Suspected)			**Reason:**	Depression
	15.0 Milligram	Daily		
Batch:	**Started:**	23/04/2002	**Stopped:**	25/04/2002

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 175982 **Seq:** 1
Reported: 04/06/2002
Hospitalisation:
Onset Date: 11/05/2002
Outcome: Recovered

Gender: F
Weight: 47.00
Age: 77
DOB: 17/05/1924
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

ATACAND (Other drug) **Reason:** Essential benign hypertension
8.0 Milligram Daily
Batch: **Started:** 01/04/2002 **Stopped:**

LASIX (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/01/1990 **Stopped:**

MINAX (Other drug) **Reason:** Essential benign hypertension
50.0 Milligram Daily
Batch: **Started:** 01/09/2001 **Stopped:**

MURELAX (Other drug) **Reason:** Anxiety neurosis
30.0 Milligram Daily
Batch: **Started:** 01/01/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 175982 **Seq:** 1
Reported: 04/06/2002
Hospitalisation:
Onset Date: 11/05/2002
Outcome: Recovered

Gender: F
Weight: 47.00
Age: 77
DOB: 17/05/1924
Causality: Causality probable

Reaction Detail

Medicine Details:

VALIUM (Other drug)		**Reason:**	Anxiety neurosis
	2.5 Milligram	Daily	
Batch:	**Started:** 01/01/1999		**Stopped:**
THYROXINE SODIUM (Other drug)		**Reason:**	Thyrotoxicosis w/o ment goiter
	100.0 Microgram	Daily	
Batch:	**Started:** 01/01/1999		**Stopped:**
AVANZA (Suspected)		**Reason:**	Anxiety neurosis
	10.0 Milligram	Daily	
Batch:	**Started:** 12/03/2002		**Stopped:** 10/05/2002

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 176079 **Seq:** 1 **Gender:** M
Reported: 06/06/2002 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 31/10/2001 **DOB:** 27/05/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Osteoarthritis		Poly arthralgia.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 28/08/2001 **Stopped:** 22/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 176118 **Seq:** 1
Reported: 06/06/2002
Hospitalisation:
Onset Date: 28/01/2002
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 33
DOB: 06/06/1968
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flushing	Severe	Severe flushing of neck skin (neck and	
Alcohol intolerance	Severe	Severe intolerance to red wine.	
Drug dependence		Tabacco craving.	
Nausea			

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 17/12/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose of mirtazapine was also taken at 45mg/daily on the 04/03/2002. the date of onset is not necessarily accurate but indicates onset sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 176225 **Seq:** 1 **Gender:** F
Reported: 11/06/2002 **Weight:**
Hospitalisation: **Age:** 90
Onset Date: 01/05/2002 **DOB:** 11/12/1911
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Generalised allergic rash from lower limbs	Date of recovery 3.5.02. treated with antihistamines.

Medicine Details:

ALENDRONATE SODIUM (Other drug) **Reason:** Other diseases of bone
10.0 Milligram Daily
Batch: **Started:** 12/03/2002 **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** 12/03/2002 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 21/04/2002 **Stopped:** 01/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 176298 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:** 78.00
Hospitalisation: **Age:** 63
Onset Date: 28/02/2002 **DOB:** 05/04/1938
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema			Withdrawal of mirtazapine, changed to venlafaxine. required a visit to doctor.

Medicine Details:

MS CONTIN (Other drug) **Reason:** Pain
80.0 Milligram Daily
Batch: **Started:** 01/01/1999 **Stopped:**

NEURONTIN (Other drug) **Reason:** Otr&unsp forms neuralg&neurit
900.0 Milligram Daily
Batch: **Started:** 01/06/2001 **Stopped:**

AVANZA (Other drug) **Reason:**
45.0 Milligram Daily
Batch: **Started:** 04/01/2002 **Stopped:** 29/03/2002

MIRTAZAPINE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 5/4/02. the date of onset is not necessarily accurate but indicates onset sometime in the month.

Report Detail

Case Number: 176301 **Seq:** 1 **Gender:** M
Reported: 17/06/2002 **Weight:** 84.00
Hospitalisation: **Age:** 81
Onset Date: 02/06/2002 **DOB:** 04/12/1920
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Dizziness			Required a visit to doctor. ceased avanza.

Medicine Details:

ADALAT OROS (Other drug) **Reason:** Essential benign hypertension
30.0 Milligram Daily
Batch: **Started:** 12/12/2001 **Stopped:**

GOPTEN (Other drug) **Reason:** Essential benign hypertension
1.0 Milligram Daily
Batch: **Started:** 25/02/2001 **Stopped:**

SOTACOR (Other drug) **Reason:** Otr&nos disord of heart rhythm
80.0 Milligram Daily
Batch: **Started:** 28/06/2001 **Stopped:**

AVANZA (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** 29/05/2002 **Stopped:** 02/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 6/6/02.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 176302 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:** 65.00
Hospitalisation: **Age:** AD
Onset Date: 28/02/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Increased appetite			Dose reduced. still on 15mg

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 04/01/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 176305 **Seq:** 1
Reported: 17/06/2002
Hospitalisation:
Onset Date: 13/05/2002
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 29
DOB: 19/01/1973
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			Avanza was ceased. date of recovery: 16/05/02.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 13/05/2002 **Stopped:** 14/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had ceased sitalopram three days earlier. avanza ceased.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 176312 **Seq:** 1 **Gender:** M
Reported: 17/06/2002 **Weight:** 90.00
Hospitalisation: **Age:** 51
Onset Date: 28/11/2001 **DOB:** 18/10/1950
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema Hyperkinesia		Quite severe periodic nocturnal leg	Reduced dose of avanza, added sertraline, treated with clonazepam. required a visit to doctor

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** 01/11/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset was sometime in the month. the dose start is not necessarily accurate but indicates avanza was started sometime in the month.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 176353 **Seq:** 1
Reported: 19/06/2002
Hospitalisation:
Onset Date: 16/06/2002
Outcome: Not yet recovered

Gender: F
Weight: 52.00
Age: A4
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscular weakness		Especially legs.	
Anorexia		Loss of appetitie.	
Dizziness			Required a visit to doctor.

Medicine Details:

EFEXOR-XR (Other drug) **Reason:** Anxiety neurosis
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:** Pain
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:**
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

EFEXOR-XR (Other drug) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also on xanax, flaxseed oil, condrotin & flucosamine at night prn.

Report Detail

Case Number: 176353 **Seq:** 1
Reported: 19/06/2002
Hospitalisation:
Onset Date: 16/06/2002
Outcome: Not yet recovered

Gender: F
Weight: 52.00
Age: A4
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

VIOXX (Other drug)		**Reason:**	Pain
	50.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
ENDEP (Other drug)		**Reason:**	Specific disorders of sleep
	25.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
AVANZA (Suspected)		**Reason:**	
	30.0 Milligram	Daily	
Batch:	**Started:** 14/06/2002		**Stopped:**

Laboratory Investigations:

Additional Information:

Patient also on xanax, flaxseed oil, condrotin & flucosamine at night prn.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 176800 **Seq:** 1 **Gender:** F
Reported: 02/07/2002 **Weight:** 55.00
Hospitalisation: **Age:** 27
Onset Date: 24/06/2002 **DOB:** 30/05/1975
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Dizziness			Date of recovery: 26/6/02. ceased avanza.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 21/06/2002 **Stopped:** 25/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms commenced with starting avanza and ceased within 24 hours of ceasing drug.

Report Detail

Case Number: 176816 **Seq:** 1 **Gender:** F
Reported: 02/07/2002 **Weight:**
Hospitalisation: **Age:** 96Y
Onset Date: 22/02/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema		Generalised oedema	

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LORAZEPAM (Other drug) **Reason:**
Tablet 0.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

OLANZAPINE (Other drug) **Reason:**
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

MIRTAZAPINE (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 176848 **Seq:** 1 **Gender:** F
Reported: 04/07/2002 **Weight:**
Hospitalisation: **Age:** A1
Onset Date: 30/06/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Avanza was ceased.

Medicine Details:

AVANZA (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 176854 **Seq:** 1 **Gender:** F
Reported: 04/07/2002 **Weight:** 137.00
Hospitalisation: **Age:** 31
Onset Date: 02/06/2002 **DOB:** 19/11/1970
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disturbance in attention			
Myalgia			
Nausea			
Pyrexia			
Serotonin syndrome			Ceased efexor and avanza. given cyproheptadine. required a visit to doctor. patient recovered 10/6/02
Tremor			

Medicine Details:

EFEXOR (Interaction) **Reason:** Depression
300.0 Milligram Daily
Batch: **Started:** 22/09/2001 **Stopped:** 31/05/2002

AVANZA (Interaction) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 01/06/2002 **Stopped:** 03/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 176861 **Seq:** 1 **Gender:** F
Reported: 04/07/2002 **Weight:** 83.00
Hospitalisation: **Age:** 43
Onset Date: **DOB:** 09/08/1958
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Nightmare Vertigo Weight increased			

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 03/06/2002 **Stopped:** 29/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 176892 **Seq:** 1
Reported: 08/07/2002
Hospitalisation:
Onset Date: 28/06/2002
Outcome: Not yet recovered

Gender: F
Weight: 63.00
Age: 32
DOB: 06/02/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukopenia Lymphopenia			Patient required a visit to

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

45.0 Milligram Daily

Batch: **Started:** 01/05/2002 **Stopped:** 01/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates that mirtazapine was started sometime in the month. past history ovarian cancer in remission for 2 years. previous exposure to venlafaxine without adverse effect.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 177122 **Seq:** 1
Reported: 15/07/2002
Hospitalisation:
Onset Date: 02/07/2002
Outcome: Recovered

Gender: M
Weight: 80.00
Age: 45
DOB: 12/01/1957
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Flatulence			Patient required a visit to doctor. date of recovery: [illegible]

Medicine Details:

EFAVIRENZ (Other drug) **Reason:** Hiv infection
600.0 Milligram Daily
Batch: **Started:** **Stopped:**

DIDANOSINE (Other drug) **Reason:** Hiv infection
400.0 Milligram Daily
Batch: **Started:** **Stopped:**

STAVUDINE (Other drug) **Reason:** Hiv infection
80.0 Milligram Daily
Batch: **Started:** **Stopped:**

PRAVACHOL (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 177122 **Seq:** 1
Reported: 15/07/2002
Hospitalisation:
Onset Date: 02/07/2002
Outcome: Recovered

Gender: M
Weight: 80.00
Age: 45
DOB: 12/01/1957
Causality: Causality probable

Reaction Detail

Medicine Details:

THYROXINE SODIUM (Other drug)			**Reason:**	Thyrotoxicosis w/o ment goiter
	50.0	Microgram	Daily	
Batch:	**Started:**	L TERM	**Stopped:**	
MIRTAZAPINE (Suspected)			**Reason:**	Depression
	20.0	Milligram	Daily	
Batch:	**Started:**	12/06/2002	**Stopped:**	05/07/2002

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 177344 **Seq:** 1 **Gender:** F
Reported: 22/07/2002 **Weight:** 87.00
Hospitalisation: **Age:** 60
Onset Date: 30/05/2002 **DOB:** 31/10/1941
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Parosmia			Patient recovered 15/7/02.

Medicine Details:

DUCENE (Other drug) **Reason:** Anxiety neurosis
2.5 Milligram As necessary
Batch: **Started:** **Stopped:**

ZOCOR (Other drug) **Reason:** Othr&unspec metabolic diseases
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

INDERAL (Other drug) **Reason:**
Oral application 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

ATACAND (Other drug) **Reason:**
8.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 177344 **Seq:** 1
Reported: 22/07/2002
Hospitalisation:
Onset Date: 30/05/2002
Outcome: Recovered

Gender: F
Weight: 87.00
Age: 60
DOB: 31/10/1941
Causality: Causality probable

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 28/05/2002 **Stopped:** 11/07/2002

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 177452 **Seq:** 1 **Gender:** M
Reported: 30/07/2002 **Weight:**
Hospitalisation: **Age:** AE
Onset Date: 15/07/2002 **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Sudden death			 Patient died 15/7/02.

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 01/07/2002 **Stopped:** 15/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 177554 **Seq:** 1 **Gender:** F
Reported: 31/07/2002 **Weight:** 79.00
Hospitalisation: **Age:** 56
Onset Date: 10/07/2002 **DOB:** 28/08/1945
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscular weakness Diarrhoea Disturbance in attention Dizziness Nightmare		Weak hands.	Ceased avanza. required a visit to doctor. patient

Medicine Details:

ESTRACOMBI (Other drug) **Reason:** Menopausal symptoms
0.0
Batch: **Started:** 01/01/1999 **Stopped:** CONTIN

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
Tablet 100.0 Microgram Daily Oral
Batch: **Started:** 01/01/1999 **Stopped:** CONTIN

AVANZA (Suspected) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** 09/07/2002 **Stopped:** 22/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 177665 **Seq:** 1 **Gender:** M
Reported: 05/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 15/07/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

REMERON (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of epilepsy.

Report Detail

Case Number: 177867 **Seq:** 1 **Gender:** M
Reported: 08/08/2002 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 25/04/2002 **DOB:** 18/08/1924
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Red confluent papules	Ceased avanza, required a visit to doctor.

Medicine Details:

NILSTAT (Other drug) **Reason:** Moniliasis
Solution 4.0 Millilitre Daily Oral
Batch: **Started:** 24/04/2002 **Stopped:** 04/05/2002

AVAPRO (Other drug) **Reason:** Chron isch heart dis no hyper
75.0 Milligram Daily
Batch: **Started:** 12/04/2002 **Stopped:** 24/04/2002

ZYLOPRIM (Other drug) **Reason:** Gout
150.0 Milligram Daily
Batch: **Started:** 12/04/2002 **Stopped:** CONTIN

ACIMAX (Other drug) **Reason:** Other diseases of esophagus
20.0 Milligram Daily
Batch: **Started:** 12/04/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to warfarin.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 177867 **Seq:** 1 **Gender:** M
Reported: 08/08/2002 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 25/04/2002 **DOB:** 18/08/1924
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

DINDEVAN (Other drug)		**Reason:**	Pulmonary embolism&infarction	
	40.0 Milligram	Daily		
Batch:	**Started:** 12/04/2002		**Stopped:**	CONTIN
ATROVENT (Other drug)		**Reason:**		
	126.0 Microgram	Daily		
Batch:	**Started:** 12/04/2002		**Stopped:**	CONTIN
SERETIDE ACCUHALER NOS (Other drug)		**Reason:**		
	4.0 Dose Unspecified	Daily		
Batch:	**Started:** 12/04/2002		**Stopped:**	CONTIN
AVANZA (Suspected)		**Reason:**	Depression	
	15.0 Milligram	Daily		
Batch:	**Started:** 23/04/2002		**Stopped:**	25/04/2002

Laboratory Investigations:

Additional Information:

Allergy to warfarin.

Report Detail

Case Number: 177873 **Seq:** 1
Reported: 09/08/2002
Hospitalisation:
Onset Date: 01/08/2002
Outcome: Not yet recovered

Gender: M
Weight: 82.00
Age: 30
DOB: 10/02/1972
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

STEMETIL FOR INJECTION (Other drug) **Reason:**
Injection 1.0 Dose Unspecified 1 time Intramuscular
Batch: **Started:** **Stopped:**

LARGACTIL (Other drug) **Reason:** Migraine
Injection 1.0 Dose Unspecified As necessary Intravenous
Batch: **Started:** **Stopped:**

MERSYNDOL FORTE (Other drug) **Reason:** Pain
Tablet 1.0 Dose Unspecified As necessary Oral
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:** Pain
Tablet 1.0 Dose Unspecified As necessary Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 177873 **Seq:** 1
Reported: 09/08/2002
Hospitalisation:
Onset Date: 01/08/2002
Outcome: Not yet recovered

Gender: M
Weight: 82.00
Age: 30
DOB: 10/02/1972
Causality: Causality possible

Reaction Detail

Medicine Details:

STEMETIL (Other drug)			**Reason:**	Nausea and vomiting	
Suppository	25.0	Milligram	As necessary		Rectal
Batch:	**Started:**			**Stopped:**	
VENTOLIN CFC-FREE INHALER (Other drug)			**Reason:**		
Inhalation	1.0	Dose Unspecified	As necessary		Inhalation
Batch:	**Started:**			**Stopped:**	
OXYCONTIN (Other drug)			**Reason:**	Migraine	
Tablet	80.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
TEMAZE (Other drug)			**Reason:**		
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 177873 **Seq:** 1
Reported: 09/08/2002
Hospitalisation:
Onset Date: 01/08/2002
Outcome: Not yet recovered

Gender: M
Weight: 82.00
Age: 30
DOB: 10/02/1972
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 10/07/2002 **Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 178125 **Seq:** 1 **Gender:** M
Reported: 16/08/2002 **Weight:** 82.00
Hospitalisation: **Age:** 45
Onset Date: 24/07/2002 **DOB:** 12/10/1956
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Date of recovery 31/07/2002. required a visit to doctor.

Medicine Details:

ENDEP (Other drug) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** **Stopped:**

PREDNISOLONE (Other drug) **Reason:** Regional enteritis
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 24/07/2002 **Stopped:** 31/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is positive rechallange. avanza was rechallenged causing the same reaction to occur.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178146 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:** 43.00
Hospitalisation: **Age:** 39Y
Onset Date: 14/08/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Somnolence Suicide attempt			Date of recovery 16.8.02.

Medicine Details:

PREDNISONE (Other drug) **Reason:** Otr&unsp difuse connec tis dis

Oral application 8.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** CONTIN

MIRTAZAPINE (Suspected) **Reason:**

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is the second of two sequences: 178145 seq 1.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178168 **Seq:** 1 **Gender:** M
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 64
Onset Date: 14/05/2002 **DOB:** 02/09/1937
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Hallucination Nightmare			Mirtazapine ceased.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/04/2002 **Stopped:** 07/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mirtazapine dose had been increased from 15mg to 30mg at night.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178287 **Seq:** 1 **Gender:** M
Reported: 15/08/2002 **Weight:** 95.00
Hospitalisation: **Age:** 57Y
Onset Date: 12/08/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disturbance in attention Malaise Somnolence			

Medicine Details:

LOSEC (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 01/01/2000 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 12/08/2002 **Stopped:** 12/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178300 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:** 86.00
Hospitalisation: **Age:** 43
Onset Date: 22/07/2002 **DOB:** 30/06/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Hyperkinesia			Date of recovery 30.7.02. avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 19/07/2002 **Stopped:** 29/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 178304 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 11/03/1964
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Increased appetite		Put on 9kg.	Mirtazapine ceased.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 06/07/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is the second of two sequences: 178303 seq 1.

Report Detail

Case Number: 178306 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 54
Onset Date: 31/07/2002 **DOB:** 27/06/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Generalised oedema	Required Specialist Consultation	Legs and arms.	Date of recovery 14.8.02. required a visit to doctor.

Medicine Details:

IRBESARTAN (Other drug) **Reason:** Essential benign hypertension
150.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

FRUSEMIDE (Other drug) **Reason:** Essential benign hypertension
20.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:**

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** 01/05/2002 **Stopped:**

PREMIA 2.5 CONTINUOUS (Other drug) **Reason:** Menopausal symptoms
2.5 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178306 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 54
Onset Date: 31/07/2002 **DOB:** 27/06/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Other drug)			**Reason:** Depression	
	25.0 Milligram	Daily		
Batch:	**Started:** 18/06/2002		**Stopped:** 08/08/2002	
AVANZA (Suspected)			**Reason:** Depression	
Tablet	30.0 Milligram	Daily		Oral
Batch:	**Started:** 16/07/2002		**Stopped:** 31/07/2002	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178431 **Seq:** 1 **Gender:** F
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Nightmare			Required a visit to doctor. ceased avanza.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** 14/08/2002 **Stopped:** 19/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178464 **Seq:** 1 **Gender:** F
Reported: 26/08/2002 **Weight:** 65.00
Hospitalisation: **Age:** 53
Onset Date: 03/06/2002 **DOB:** 03/02/1949
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Required Visit to Doctor		Patient required a visit to doctor. date of recovery: 18/7/02

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 03/05/2002 **Stopped:** 18/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178488 **Seq:** 1 **Gender:** F
Reported: 26/08/2002 **Weight:**
Hospitalisation: **Age:** 69
Onset Date: 06/05/2002 **DOB:** 20/09/1932
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Required Visit to Doctor		Patient required a visit to doctor. date of recovery: 06/8/02. temporary withdrawal and reintroduced

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 06/05/2002 **Stopped:** 30/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178491 **Seq:** 1 **Gender:** F
Reported: 26/08/2002 **Weight:** 73.00
Hospitalisation: **Age:**
Onset Date: 10/08/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare			Patient required a visit to

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 06/08/2002 **Stopped:** 22/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178515 **Seq:** 1 **Gender:** F
Reported: 28/08/2002 **Weight:** 56.00
Hospitalisation: **Age:** 41
Onset Date: 01/08/2002 **DOB:** 03/10/1960
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Myalgia Somnolence		Polyarthralgia.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 30/07/2001 **Stopped:** 13/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 178558 **Seq:** 1
Reported: 30/08/2002
Hospitalisation:
Onset Date: 13/08/2002
Outcome: Not yet recovered

Gender: M
Weight: 108.00
Age: 50Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Try ceasing first mirtazapine and then olanzopine.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram As necessary Oral
Batch: **Started:** 01/08/2002 **Stopped:**

OLANZAPINE (Suspected) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 01/04/2002 **Stopped:** 03/08/2002

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/08/2002 **Stopped:**

LORAZEPAM (Suspected) **Reason:** Depression
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 01/08/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils				Neutrophil count 1.46.

Additional Information:

The dose start dates are not necessarily accurate but indicates mirtazapine, lorazepam, chlorpramazine, olanzopine were started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178702 **Seq:** 1
Reported: 03/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 15/08/2002
Outcome: Unknown

Gender: U
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal failure acute			Patient was hospitalised.

Medicine Details:

AVANZA (Suspected) **Reason:**

Tablet 0.0 Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report - 178702 is a duplicate of 178741.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178735 **Seq:** 1
Reported: 05/09/2002
Hospitalisation:
Onset Date: 30/08/2002
Outcome: Not yet recovered

Gender: M
Weight: 80.00
Age: 39
DOB: 14/01/1963
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Hyperhidrosis Nausea			Required a visit to doctor.

Medicine Details:

STILNOX (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

NEXIUM (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

MOTILIUM (Other drug) **Reason:**
3.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

PANAMAX (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178735 **Seq:** 1
Reported: 05/09/2002
Hospitalisation:
Onset Date: 30/08/2002
Outcome: Not yet recovered

Gender: M
Weight: 80.00
Age: 39
DOB: 14/01/1963
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 178916 **Seq:** 1 **Gender:** F
Reported: 09/09/2002 **Weight:**
Hospitalisation: **Age:** A4
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nightmare			Ceased mirtazapine.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 178930 **Seq:** 1 **Gender:** F
Reported: 10/09/2002 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare			Ceased mirtazapine.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 178973 **Seq:** 1
Reported: 12/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 31/07/2002
Outcome: Recovered

Gender: M
Weight:
Age: 41
DOB: 16/08/1960
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			
Confusional state			
Diarrhoea			
Dyspnoea			
Hypertonia			
Myalgia			Admitted to hospital.
Tremor			

Medicine Details:

AVANZA (Interaction) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 26/05/2002 **Stopped:** 29/07/2002

AURORIX (Interaction) **Reason:** Depression

Tablet 450.0 Milligram Daily Oral

Batch: **Started:** 31/07/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Serotonin syndrome.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179037 **Seq:** 1
Reported: 16/09/2002
Hospitalisation:
Onset Date: 04/09/2002
Outcome: Not yet recovered

Gender: F
Weight: 101.00
Age: 44
DOB: 17/12/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Aching thighs.	
Oedema		Pitting oedema bilaterally.	

Medicine Details:

COVERSYL (Other drug) **Reason:** Essential benign hypertension
0.0
Batch: **Started:** L TERM **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/08/2002 **Stopped:** 12/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking norday 2 dosage form daily (8 yrs).

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179043 **Seq:** 1 **Gender:** F
Reported: 16/09/2002 **Weight:** 62.00
Hospitalisation: **Age:** 67
Onset Date: 30/08/2002 **DOB:** 15/05/1935
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Altered perception of time.	
Abnormal dreams		Vivid dreams.	Medication ceased.
Apathy			
Depersonalisation			
Dry mouth			
Somnolence			

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 30/08/2002 **Stopped:** 02/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179049 **Seq:** 1 **Gender:** F
Reported: 16/09/2002 **Weight:** 135.00
Hospitalisation: **Age:** 43
Onset Date: 21/06/2002 **DOB:** 12/03/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Patient required a visit to doctor. avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 17/05/2002 **Stopped:** 18/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT				70 (n40) desc: returned to normal with ceasing drug.

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179281 **Seq:** 1 **Gender:** F
Reported: 19/09/2002 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 09/09/2002 **DOB:** 08/10/1954
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Arms and legs.	Treated with hydrocortisone cream. mirtazapine ceased. required a visit to doctor.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 03/09/2002 **Stopped:** 10/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug positive rechallenge. had previously been on mirtazapine and ceased it due to a similar rash developing.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179348 **Seq:** 1
Reported: 23/09/2002
Hospitalisation:
Onset Date: 15/09/2002
Outcome: Not yet recovered

Gender: F
Weight: 63.00
Age: 86
DOB: 29/07/1916
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular Pruritus		Macular rash whole body.	Antroquoril cream, phenergan dose increased. required a visit

Medicine Details:

DAPA-TABS (Other drug) **Reason:** Essential benign hypertension
2.5 Milligram Daily
Batch: **Started:** 06/02/2002 **Stopped:** CONTIN

SOMAC (Other drug) **Reason:** Other diseases of esophagus
40.0 Milligram Daily
Batch: **Started:** 22/01/2002 **Stopped:** CONTIN

PREDNISOLONE (Other drug) **Reason:** Other rheumatoid arthritis
7.5 Milligram Daily
Batch: **Started:** 13/12/2001 **Stopped:** CONTIN

OXYCONTIN (Other drug) **Reason:** Other rheumatoid arthritis
20.0 Milligram Daily
Batch: **Started:** 15/04/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 179348 **Seq:** 1
Reported: 23/09/2002
Hospitalisation:
Onset Date: 15/09/2002
Outcome: Not yet recovered

Gender: F
Weight: 63.00
Age: 86
DOB: 29/07/1916
Causality: Causality possible

Reaction Detail

Medicine Details:

PARACETAMOL (Other drug)		**Reason:**	Other rheumatoid arthritis	
	4.0 Gram	Daily		
Batch:	**Started:** 19/12/2001		**Stopped:**	CONTIN
METHOBLASTIN (Suspected)		**Reason:**	Other rheumatoid arthritis	
Tablet	5.0 Milligram	Weekly	Oral	
Batch:	**Started:** 07/05/2002		**Stopped:**	18/09/2002
AVANZA (Suspected)		**Reason:**	Depression	
Tablet	30.0 Milligram	Daily	Oral	
Batch:	**Started:** 14/08/2002		**Stopped:**	18/09/2002

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179367 **Seq:** 1
Reported: 25/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/09/2002
Outcome: Recovered

Gender: F
Weight:
Age: 15
DOB: 25/02/1987
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia Grand mal convulsion			Patient was hospitalised.

Medicine Details:

REMERON (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 10/08/2002 **Stopped:** 14/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient with a positive family history. the time interval between start of remeron and the onset of the convulsions is rather long, but an additional role of the preceding viral infection is possible.

Report Detail

Case Number: 179410 **Seq:** 1 **Gender:** M
Reported: 26/09/2002 **Weight:** 80.00
Hospitalisation: **Age:** 26
Onset Date: **DOB:** 02/06/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Took overdose.	Patient recovered 20/7/02.

Medicine Details:

AMISULPRIDE (Suspected) **Reason:**
Tablet 5.6 Gram Total Oral
Batch: **Started:** 17/07/2002 **Stopped:**

ZOPICLONE (Suspected) **Reason:**
Tablet 105.0 Milligram Total Oral
Batch: **Started:** 17/07/2002 **Stopped:**

CARBAMAZEPINE (Suspected) **Reason:**
Tablet 2.8 Gram Total Oral
Batch: **Started:** 17/07/2002 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet 210.0 Milligram Total Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179433 **Seq:** 1
Reported: 27/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 16/07/2002
Outcome: Recovered

Gender: F
Weight: 70.00
Age: 70
DOB: 22/07/1931
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Patient was hospitalised. date of recovery: 24/9/02. patient required catheterization.

Medicine Details:

COLOXYL WITH SENNA (Other drug) **Reason:**
4.0 Dose Unspecified As necessary
Batch: **Started:** S TERM **Stopped:** CONTIN

MIRTAZAPINE (Other drug) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 16/07/2002

PANTOPRAZOLE (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:** CONTIN

TEMAZEPAM (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 179433 **Seq:** 1
Reported: 27/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 16/07/2002
Outcome: Recovered

Gender: F
Weight: 70.00
Age: 70
DOB: 22/07/1931
Causality: Causality probable

Reaction Detail

Medicine Details:

MAXOLON (Other drug)			**Reason:**		
	30.0 Milligram	Daily			
Batch:	**Started:**	S TERM	**Stopped:**	CONTIN	
MIRTAZAPINE (Suspected)			**Reason:**	Depression	
Tablet	0.0			Oral	
Batch:	**Started:**	16/07/2002	**Stopped:**	21/09/2002	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179473 **Seq:** 1
Reported: 30/09/2002
Hospitalisation:
Onset Date: 20/08/2002
Outcome: Recovered

Gender: F
Weight: 80.00
Age: 38
DOB: 06/10/1963
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			Required a visit to doctor. date of recovery 27/08/02

Medicine Details:

AVANZA (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** 01/07/2002 **Stopped:** 21/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates the drug was sta rted sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179484 **Seq:** 1 **Gender:** M
Reported: 30/09/2002 **Weight:** 80.00
Hospitalisation: **Age:** 79
Onset Date: 31/08/2002 **DOB:** 12/12/1922
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state		Acute confusion.	
Delirium		Acute delirium.	Patient required a visit to doctor. date of recovery: 3/9/02
Hallucination			

Medicine Details:

DIAFORMIN (Other drug) **Reason:** Diabetes mellitus
1.0 Gram Daily
Batch: **Started:** L TERM **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 29/08/2002 **Stopped:** 02/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 179509 **Seq:** 1 **Gender:** M
Reported: 01/10/2002 **Weight:**
Hospitalisation: **Age:** 71
Onset Date: 07/08/2002 **DOB:** 25/06/1931
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia Pneumonia	Life	Life threatening.	Cessation of both olanzapine and mirtazapine. treated with amoxycillin and metronidazole. patient deceased on 09/08/02.

Medicine Details:

AMOXYCILLIN SODIUM (Other drug) **Reason:**
Oral application 2.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

METRONIDAZOLE (Other drug) **Reason:**
Oral application 1.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

PRAZOSIN HYDROCHLORIDE (Other drug) **Reason:**
Oral application 4.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

OXAZEPAM (Other drug) **Reason:**
Oral application 130.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology Radiololgy				Neutrophils 0.58, lylmphocytes 0.32, monocytes 0.11, eosinophils 0.03. wcc 1.6, rcc 3.99, hct 0.39. moderate neutropenia, with a left shift Chest x-ray shows right sided patchy opacity.

Additional Information:

Prior history of aspiration pneumonia.

Report Detail

Case Number: 179509 **Seq:** 1
Reported: 01/10/2002
Hospitalisation:
Onset Date: 07/08/2002
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 71
DOB: 25/06/1931
Causality: Causality possible

Reaction Detail

Medicine Details:

SENOKOT (Other drug)			**Reason:**		
Tablet	2.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
TEMAZEPAM (Other drug)			**Reason:**		
Oral application	10.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
PARACETAMOL (Other drug)			**Reason:**		
Oral application	4.0	Gram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
MIRTAZAPINE (Suspected)			**Reason:**		
Tablet	0.0				Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:
Prior history of aspiration pneumonia.

Report Detail

Case Number: 179509 **Seq:** 1
Reported: 01/10/2002
Hospitalisation:
Onset Date: 07/08/2002
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 71
DOB: 25/06/1931
Causality: Causality possible

Reaction Detail

Medicine Details:

OLANZAPINE (Suspected)			**Reason:**	
Tablet	10.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Additional Information:
Prior history of aspiration pneumonia.

Report Detail

Case Number: 179531 **Seq:** 1 **Gender:** F
Reported: 02/10/2002 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 17/06/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukopenia Thrombocytopenia			Reactions moderate.

Medicine Details:

AUGMENTIN FORTE (Other drug) **Reason:**
0.0
Batch: **Started:** 14/06/2002 **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:**

LACTULOSE (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:**

PARACETAMOL (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets	(N:150-400)	17/06/2002	140	
	Platelets	(N:150-400)	18/06/2002	126	
	Platelets	(N:150-400)	20/06/2002	151	
	Platelets	(N:150-400)	19/06/2002	130	
	White blood cells	(N:4-11)	17/06/2002	3.3	
	White blood cells	(N:4-11)	18/06/2002	3.6	
	White blood cells	(N:4-11)	19/06/2002	402	

Additional Information:

Patient also taking - cartia.

Report Detail

Case Number: 179531 **Seq:** 1 **Gender:** F
Reported: 02/10/2002 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 17/06/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

DOMPERIDONE (Other drug)			**Reason:**		
Oral application	40.0	Milligram	As necessary	Oral	
Batch:	**Started:** 27/05/2002			**Stopped:**	
NOTEN (Other drug)			**Reason:**		
Oral application	50.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
KINSON (Other drug)			**Reason:**		
Oral application	0.0		Daily	Oral	
Batch:	**Started:**			**Stopped:**	
ARICEPT (Other drug)			**Reason:**		
Oral application	10.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	(N:4-11)	20/06/2002	5.1	

Additional Information:

Patient also taking - cartia.

Report Detail

Case Number: 179531 **Seq:** 1 **Gender:** F
Reported: 02/10/2002 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 17/06/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

F.G.F. (Other drug)			**Reason:**		
Oral application	0.0		Daily		Oral
Batch:	**Started:**	25/05/2002		**Stopped:**	
HEPARIN SODIUM (Other drug)			**Reason:**		
	5.0	Thousand Internat	Daily		
Batch:	**Started:**			**Stopped:**	
MIRTAZAPINE (Suspected)			**Reason:**		
Tablet	7.5	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	19/06/2002
FOLIC ACID (Suspected)			**Reason:**		
Tablet	5.0	Milligram	Daily		Oral
Batch:	**Started:**	27/05/2002		**Stopped:**	16/06/2002

Laboratory Investigations:

Additional Information:

Patient also taking - cartia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179770 **Seq:** 1 **Gender:** F
Reported: 08/10/2002 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: 26/09/2002 **DOB:** 22/06/1947
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		While asleep.	Patient required a visit to doctor. date of recovery: [illegible]

Medicine Details:

COVERSYL PLUS (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 22/03/2002 **Stopped:**

FELODIPINE (Other drug) **Reason:**
2.5 Milligram Daily
Batch: **Started:** 24/05/2002 **Stopped:**

PROGYNOVA (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** 13/11/2001 **Stopped:**

SOLPRIN (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** 25/01/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No patient history of seizures.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 179770 **Seq:** 1 **Gender:** F
Reported: 08/10/2002 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: 26/09/2002 **DOB:** 22/06/1947
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 30/08/2002 **Stopped:** 01/10/2002

Laboratory Investigations:

Additional Information:

No patient history of seizures.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180006 **Seq:** 1 **Gender:** M
Reported: 21/10/2002 **Weight:** 65.00
Hospitalisation: **Age:** 27Y
Onset Date: 11/10/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema Abdominal distension		Bilateral oedema of ankles & feet. Possible abdominal distension.	

Medicine Details:

ALPRAZOLAM (Other drug) **Reason:**
Oral application 4.0 Milligram Daily Oral
Batch: **Started:** 01/10/2002 **Stopped:**

BUPRENORPHINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** 25/09/2002 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/10/2002 **Stopped:** 14/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180027 **Seq:** 1
Reported: 23/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 10/10/2002
Outcome: Recovered

Gender: M
Weight: 110.00
Age: 56
DOB: 21/01/1946
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope Vomiting			Patient was hospitalised and required a visit to doctor. date of recovery: 11/10/02.

Medicine Details:

LIGNOCAINE HYDROCHLORIDE AND ADRENALINE (Suspected) **Reason:**
Injection 15.0 Millilitre 1 time Intravenous
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/04/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for avanza is not necessarily accurate but indicates the drug was started sometime in the month.

Report Detail

Case Number: 180045 **Seq:** 1
Reported: 24/10/2002
Hospitalisation:
Onset Date: 05/09/2002
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 52
DOB: 08/12/1949
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

CALTRATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

NEO-MERCAZOLE (Other drug) **Reason:**
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

XANAX (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 26/08/2002 **Stopped:** 10/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/10/2002	ALT = SGPT	0-45	01/08/2000	21	
24/10/2002	ALT = SGPT	0-45	12/06/2001	14	
24/10/2002	ALT = SGPT	0-45	05/09/2002	77	
24/10/2002	ALT = SGPT	0-45	24/09/2002	184	
24/10/2002	ALT = SGPT	0-45	26/11/2002	58	
24/10/2002	ALT = SGPT	0-45	17/10/2002	153	
24/10/2002	AST = SGOT	11-38	01/08/2000	22	

Additional Information:

Report Detail

Case Number: 180045 **Seq:** 1
Reported: 24/10/2002
Hospitalisation:
Onset Date: 05/09/2002
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 52
DOB: 08/12/1949
Causality: Causality possible

Reaction Detail

Medicine Details:

CALTRATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

NEO-MERCAZOLE (Other drug) **Reason:**
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

XANAX (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 26/08/2002 **Stopped:** 10/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/10/2002	AST = SGOT	11-38	05/09/2002	66	
24/10/2002	AST = SGOT	11-38	24/09/2002	108	
24/10/2002	AST = SGOT	11-38	26/11/2002	33	
24/10/2002	AST = SGOT	11-38	17/10/2002	63	
24/10/2002	AST = SGOT	11-38	12/06/2001	21	
24/10/2002	Bilirubin	0-17	01/08/2000	6	
24/10/2002	Bilirubin	0-17	12/06/2001	7	

Additional Information:

Report Detail

Case Number: 180045 **Seq:** 1
Reported: 24/10/2002
Hospitalisation:
Onset Date: 05/09/2002
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 52
DOB: 08/12/1949
Causality: Causality possible

Reaction Detail

Medicine Details:

CALTRATE (Other drug)				**Reason:**	
	0.0				
Batch:	**Started:**			**Stopped:**	
NEO-MERCAZOLE (Other drug)				**Reason:**	
Tablet	0.5	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
XANAX (Other drug)				**Reason:**	
	1.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
AVANZA (Suspected)				**Reason:**	Depression
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**	26/08/2002		**Stopped:**	10/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/10/2002	Bilirubin	0-17	05/09/2002	6	
24/10/2002	Bilirubin	0-17	24/09/2002	6	
24/10/2002	Bilirubin	0-17	17/10/2002	5	
24/10/2002	Bilirubin	0-17	26/11/2002	5	
24/10/2002	GGT = SGGT =	0-45	01/08/2000	33	
24/10/2002	GGT = SGGT =	0-45	12/06/2001	39	
24/10/2002	GGT = SGGT =	0-45	24/09/2002	319	

Additional Information:

Report Detail

Case Number: 180045 **Seq:** 1
Reported: 24/10/2002
Hospitalisation:
Onset Date: 05/09/2002
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 52
DOB: 08/12/1949
Causality: Causality possible

Reaction Detail

Medicine Details:

CALTRATE (Other drug)				**Reason:**	
	0.0				
Batch:	**Started:**			**Stopped:**	
NEO-MERCAZOLE (Other drug)				**Reason:**	
Tablet	0.5	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
XANAX (Other drug)				**Reason:**	
	1.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
AVANZA (Suspected)				**Reason:**	Depression
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**	26/08/2002		**Stopped:**	10/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/10/2002	GGT = SGGT =	0-45	26/11/2002	105	
24/10/2002	GGT = SGGT =	0-45	17/10/2002	325	
24/10/2002	GGT = SGGT =	0-45	05/09/2002	80	
24/10/2002	SAP = ALP	42-142	01/08/2000	72	
24/10/2002	SAP = ALP	42-142	12/06/2001	58	
24/10/2002	SAP = ALP	42-142	05/09/2002	76	
24/10/2002	SAP = ALP	42-142	24/09/2002	221	

Additional Information:

Report Detail

Case Number: 180045 **Seq:** 1
Reported: 24/10/2002
Hospitalisation:
Onset Date: 05/09/2002
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 52
DOB: 08/12/1949
Causality: Causality possible

Reaction Detail

Medicine Details:

CALTRATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

NEO-MERCAZOLE (Other drug) **Reason:**
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

XANAX (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 26/08/2002 **Stopped:** 10/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/10/2002	SAP = ALP	42-142	17/10/2002	211	
24/10/2002	SAP = ALP	42-142	26/11/2002	107	

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180103 **Seq:** 1 **Gender:** F
Reported: 28/10/2002 **Weight:** 85.00
Hospitalisation: **Age:** 42
Onset Date: 30/09/2002 **DOB:** 26/12/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Hepatic function abnormal Malaise Myalgia	Severe	Polyarthralgia, polymyalagia, severe	Required a visit to doctor.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 25/04/2002 **Stopped:** 18/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Immunology				Abc, eb serology all negative.

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180120 **Seq:** 1 **Gender:** M
Reported: 28/10/2002 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 08/09/2002 **DOB:** 25/10/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Drug overdose	Observation

Medicine Details:

TEMAZEPAM (Other drug) **Reason:**
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

VENLAFAXINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

OXAZEPAM (Suspected) **Reason:**
Tablet 120.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is a seq of 180121.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180122 **Seq:** 1
Reported: 28/10/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: U
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope			Patient was admitted to

Medicine Details:

AVANZA (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 180244 **Seq:** 1
Reported: 31/10/2002
Hospitalisation:
Onset Date: 07/10/2002
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 50
DOB: 05/09/1952
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Severe	Severe	Patient required a visit to

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 01/10/2002 **Stopped:** 24/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180270 **Seq:** 1
Reported: 31/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 15/10/2002
Outcome: Recovered

Gender: F
Weight: 100.00
Age: 31
DOB: 15/09/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aphasia Confusional state Delusion Hallucination Hyperacusis Paranoia Psychotic disorder			Im largactyl administered. patient was admitted to hospital. recovered 16/10/02.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 06/10/2002 **Stopped:** 15/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Psychotic episode and increased sensitivity to noise. psychotic reaction was of a paranoid nature. delusion (fixed). auditory hallucinations preceded confusion leading up to and during incoterent (speech).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180340 **Seq:** 1
Reported: 04/11/2002
Hospitalisation:
Onset Date: 29/08/2002
Outcome: Recovered

Gender: M
Weight: 81.00
Age: 62
DOB: 12/10/1939
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Recovered 30/8/02.

Medicine Details:

OMEGA-3 MARINE TRIGLYCERIDES (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

NORVASC (Other drug) **Reason:** Essential benign hypertension
5.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

COVERSYL (Other drug) **Reason:** Essential benign hypertension
6.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

LASIX (Other drug) **Reason:** Essential benign hypertension
1.0 Dose Unspecified Daily
Batch: **Started:** 01/01/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180340 **Seq:** 1
Reported: 04/11/2002
Hospitalisation:
Onset Date: 29/08/2002
Outcome: Recovered

Gender: M
Weight: 81.00
Age: 62
DOB: 12/10/1939
Causality: Causality possible

Reaction Detail

Medicine Details:

DIAMICRON (Other drug)		**Reason:**	Diabetes mellitus
	0.5 Dose Unspecified Daily		
Batch:	**Started:** 01/01/2000		**Stopped:**
AVANZA (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 180566 **Seq:** 1 **Gender:** F
Reported: 11/11/2002 **Weight:** 65.00
Hospitalisation: **Age:** 72
Onset Date: 09/10/2002 **DOB:** 23/02/1930
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia Weight increased			Required a visit to doctor.

Medicine Details:

SEREPAX (Other drug) **Reason:** Anxiety neurosis
30.0 Milligram Daily
Batch: **Started:** 01/01/1990 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 09/10/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180570 **Seq:** 1 **Gender:** M
Reported: 11/11/2002 **Weight:**
Hospitalisation: **Age:** 63
Onset Date: 03/09/2002 **DOB:** 03/09/1939
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Required a visit to doctor. recovered 3/9/02.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 26/08/2002 **Stopped:** 03/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180602 **Seq:** 1 **Gender:** F
Reported: 13/11/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 04/11/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Neurosis			Stopped avanza.

Medicine Details:

OXAZEPAM (Other drug) **Reason:** Depression
30.0 Milligram As necessary
Batch: **Started:** **Stopped:**

DEPTRAN (Other drug) **Reason:** Depression
150.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 04/11/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180605 **Seq:** 1 **Gender:** F
Reported: 13/11/2002 **Weight:** 95.00
Hospitalisation: **Age:** 60
Onset Date: 05/11/2002 **DOB:** 09/08/1942
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Confusional state Drug withdrawal syndrome Dry mouth Fatigue Hyperhidrosis Thirst		Hypersomina	Stopped avanza, halve dose first. required a visit to doctor. recovered 8/11/02.

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug) **Reason:** Diabetes mellitus
3.0 Gram Daily
Batch: **Started:** 01/01/1997 **Stopped:**

ATACAND (Other drug) **Reason:** Essential benign hypertension
8.0 Milligram Daily
Batch: **Started:** 01/01/1999 **Stopped:**

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
10.0 Milligram Daily
Batch: **Started:** 01/01/2001 **Stopped:**

OGEN (Other drug) **Reason:** Menopausal symptoms
625.0 Microgram Daily
Batch: **Started:** 01/01/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is a seq of 180605.

Report Detail

Case Number: 180605 **Seq:** 1
Reported: 13/11/2002
Hospitalisation:
Onset Date: 05/11/2002
Outcome: Recovered

Gender: F
Weight: 95.00
Age: 60
DOB: 09/08/1942
Causality: Causality possible

Reaction Detail

Medicine Details:

OROXINE (Other drug)		**Reason:** Toxic diffuse goiter	
	150.0 Milligram	Daily	
Batch:	**Started:** 01/01/1986		**Stopped:**
AVANZA (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
CIPRAMIL (Suspected)		**Reason:** Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	**Started:** 01/01/2001		**Stopped:** 03/11/2002

Laboratory Investigations:

Additional Information:

This report is a seq of 180605.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180606 **Seq:** 1 **Gender:** F
Reported: 13/11/2002 **Weight:** 95.00
Hospitalisation: **Age:** 60
Onset Date: 05/11/2002 **DOB:** 09/08/1942
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Confusional state Depression Dry mouth Fatigue Hyperhidrosis Thirst		Hypersomina	Stopped avanza, halve dose first. required a visit to doctor. recovered 8/11/02.

Medicine Details:

AVANZA (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is a seq of 180605.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180640 **Seq:** 1 **Gender:** F
Reported: 15/11/2002 **Weight:**
Hospitalisation: **Age:** 22
Onset Date: 12/11/2002 **DOB:** 20/02/1980
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand mal epilipsy	Required a visit ot doctor.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 12/11/2002 **Stopped:** 13/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had a fit a few hours after the 1st prescribed tablet of avanza 30mg.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180759 **Seq:** 1 **Gender:** F
Reported: 18/12/2002 **Weight:** 59.00
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Required Visit to Doctor	Weight gain - 53 to 59 kg in 2/12.	Increased exercise (walks 40 minutes every day).

Medicine Details:

LEVLEN ED (Suspected) **Reason:** Contraception
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 15/12/2001 **Stopped:** 29/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of onset was approximately December 2001.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180761 **Seq:** 1 **Gender:** F
Reported: 18/12/2002 **Weight:** 104.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 30/07/1969
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia	Required Visit to Doctor	Within an hour of taking Avanza, R upper leg myalgia spasm, R hip ache/pain, kept her awake at night. Recurred on rechallenge	
Arthralgia	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 45.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180765 **Seq:** 1 **Gender:** M
Reported: 18/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 84
Onset Date: **DOB:** 15/02/1918
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence	Life	Very drowsy, extreme hypertonicity.	Oral Roxithromycin, Salbutamo Nebuliser and Ipratropium
Hypertonia	Life		
Serotonin syndrome	Life		

Medicine Details:

AVANZA (Interaction) **Reason:** Unspecified psychosis
Tablet 30.0 Milligram Oral
Batch: **Started:** 29/04/2002 **Stopped:** 18/09/2002

REMINYL (Interaction) **Reason:**
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 26/08/2002 **Stopped:** 18/09/2002

ZYPREXA (Interaction) **Reason:** Unspecified psychosis
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 18/09/2002 **Stopped:**

DIGOXIN (Other drug) **Reason:**
62.5 Microgram
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/12/2002	Other data				

Additional Information:

Patient was also taking Zyprexa 5mg, Warfarin 5mg and Lasix 40mg.
Patient hsitory: Anaemia of chronic disease/mild renal impairment prior to starting galatamine and with mild mixed dementing illness - diagnosed July 02 as probable athrosclerotic disease and extensive small vessel cerebrovascular disease and a long history of major depression query psychotic element. He also had a history of atrial fibrillation and congestive cardiac failure. Clin Microbiol Infect 2003; 9: 1215-1218.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180774 **Seq:** 1 **Gender:** F
Reported: 18/12/2002 **Weight:** 50.00
Hospitalisation: **Age:** 17
Onset Date: **DOB:** 07/12/1985
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Diarrhoea Dizziness Malaise		Taking 60 mg mirtazapine daily: trialled a test dose of 12.5 mg sertraline in combination. Two hours later felt unwell, nauseous, whoozy and had diarrhoea. This lasted several hours.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 12.5 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Interaction) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ORAL CONTRACEPTIVE NOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 180870 **Seq:** 1 **Gender:** M
Reported: 19/12/2002 **Weight:** 105.00
Hospitalisation: **Age:** 19Y
Onset Date: 04/11/2002 **DOB:**
Outcome: Recovered 19/11/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Dehydration Depression		Suicidal thoughts, dehydrated	Withdrawal of Avanza

Medicine Details:

MAXOLON (Other drug) **Reason:**

Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Anxiety neurosis

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 07/10/2002 **Stopped:** 16/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Imipramine did the same, cipramil did not

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180896 **Seq:** 1 **Gender:** M
Reported: 20/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 80
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare		Ptient had nightmares when starting Avanza and when the dose was increased. This occurred 3 times.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 02/04/2002 **Stopped:** CONTIN

ARICEPT (Suspected) **Reason:** Unspecified psychosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 02/04/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 180919 **Seq:** 1 **Gender:** F
Reported: 20/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 65
Onset Date: 03/11/2002 **DOB:** 05/09/1937
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia	Life	thrombocytopenia	
Haemorrhage	Life		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HEPARIN SODIUM (Suspected) **Reason:** Other coagulation defects
Injection 5.0 Thousand Internat Daily Subcutaneous
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:** Other&unspecified epilepsy
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

DIPYRIDAMOLE (Suspected) **Reason:** Other coagulation defects
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/12/2002	Platelets	150 - 450	24/10/2002	286	
20/12/2002	Platelets	150 - 450	03/11/2002	90	
20/12/2002	Platelets	150 - 450	04/11/2002	39	
20/12/2002	Platelets	150 - 450	05/11/2002	11	
20/12/2002	Platelets	150 - 450	06/11/2002	12	

Additional Information:

Patient's history - Thrombocytopenia. Patient also taking Sinemet, Aluminium hydroxide gel, Insulin, Phenytoin, Mixtard, Vancomycin, Ceftriaxone, Cefalexin, Timentin.
History of Myocardial ischaemia, hypertension and cerebrovascular accident.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 180957 **Seq:** 1 **Gender:** F
Reported: 21/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 64
Onset Date: 07/07/2002 **DOB:** 16/10/1937
Outcome: Recovered 10/07/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention		Unable to void distended bladder.	Mirtazepine ceased. in-dwelling catheter

Medicine Details:

SALBUTAMOL (Other drug) **Reason:**
Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

PREMARIN (Other drug) **Reason:**
Tablet 300.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 09/05/2002 **Stopped:** 08/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Folic Acid, Multivitamins, ramipril, alendronate, seretride, panadol, ostelin, prednisolone, atrovent, diazepam.

Report Detail

Case Number: 181014 **Seq:** 1
Reported: 02/01/2003
Hospitalisation: Admitted to hospital
Onset Date: 07/10/2002
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 85
DOB: 09/06/1917
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiac failure	Caused or prolonged inpatient hospitalisation	Cardiac Failure, Oedema, Chest Pain	
Chest pain	Caused or prolonged inpatient hospitalisation		
Oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SALBUTAMOL (Other drug) **Reason:** Asthma

Inhalation		Dose Unspecified	Daily	Inhalation	
Batch:	**Started:**			**Stopped:**	CONTIN

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep

Oral application	10.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

AVANZA (Suspected) **Reason:**

Tablet	15.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking other drugs - Ranitidine and Coloxyl with Senna. Relevant history - Anxiety, insomnia, attacks of breathlessness, duodenal ulcer and hintus hernia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181143 **Seq:** 1 **Gender:** F
Reported: 07/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 85
Onset Date: 18/11/2002 **DOB:** 28/03/1917
Outcome: Recovered 21/11/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemin	

Medicine Details:

DILTIAZEM HYDROCHLORIDE (Other drug) **Reason:** Essential benign hypertension
Capsule 240.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

PANTOPRAZOLE (Other drug) **Reason:** Other diseases of esophagus
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 12/11/2002 **Stopped:** 20/11/2002

ETOPOSIDE (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 12/11/2002 **Stopped:** 21/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181180 **Seq:** 1 **Gender:** F
Reported: 07/01/2003 **Weight:** 55.00
Hospitalisation: **Age:** 40
Onset Date: 20/11/2002 **DOB:** 04/08/1962
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral Increased appetite		Fluid retention, pitting oedema in lower legs aslo an increase in appetite.	

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181268 **Seq:** 1 **Gender:** M
Reported: 09/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 63
Onset Date: 30/11/2002 **DOB:** 05/06/1939
Outcome: Recovered 02/12/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Myalgia Somnolence Tremor		Somnolence, Shaking and Shivering, sore flanks and slept for 13 hours straight.	

Medicine Details:

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
40.0 Milligram Daily
Batch: **Started:** 19/10/2002 **Stopped:**

TENORMIN (Other drug) **Reason:** Essential benign hypertension
Tablet Daily Oral
Batch: **Started:** 23/08/2002 **Stopped:**

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet Milligram Daily Oral
Batch: **Started:** 30/11/2002 **Stopped:** 01/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Kalma, Solprin, Karvea.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181292 **Seq:** 1 **Gender:** M
Reported: 09/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: 04/07/2002 **DOB:** 10/02/1973
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	Romeron reduced and ceased

Medicine Details:

RISPERIDONE (Other drug) **Reason:** Anxiety neurosis

Tablet 3.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** CONTIN

REMERON (Suspected) **Reason:**

Tablet 45.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2003	Haemoglobin	135 - 175			
09/01/2003	Neutrophils	1.8 - 8.0			
09/01/2003	White blood cells	4 - 11.0			

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181293 **Seq:** 1 **Gender:** U
Reported: 09/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsions	

Medicine Details:

REMERON (Suspected) **Reason:**

Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181429 **Seq:** 1 **Gender:** F
Reported: 13/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 64
Onset Date: 28/10/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Tardive dyskinesia	Cessation of avanza

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 13/09/2002 **Stopped:** 12/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking antenex, nexium, seretide, ventolin.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181510 **Seq:** 1 **Gender:** F
Reported: 14/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 18
Onset Date: 16/10/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Anxiety Myalgia Weight increased		Agression, anxiety attacks, weight gain, general muscle aches and pains.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 08/10/2002 **Stopped:** 21/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of asthma, panic attacks and bulimia.
Patient also taking Salbutamol, Fluticasone Propionate and Diazepam.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181511 **Seq:** 1 **Gender:** M
Reported: 14/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 02/11/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Irritability Myalgia		Agression, irritability, muscle aches and pains especially lower back.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 18/10/2002 **Stopped:** 02/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181575 **Seq:** 1 **Gender:** F
Reported: 14/01/2003 **Weight:** 47.00
Hospitalisation: **Age:** 36
Onset Date: 12/11/2002 **DOB:** 21/09/1966
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anaemia	Caused or prolonged inpatient hospitalisation	Anaemia, leukopenia, neutropenia,	
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation	Hepatic function abnormal, lactate dehydrogenase activity increased.	
Lymphadenopathy	Caused or prolonged inpatient hospitalisation	Lymphadenopathy, pain; severe pain in body	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 08/11/2002 **Stopped:** 20/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2003	Haemoglobin	115 -160	19/11/2002	98	
14/01/2003	Haemoglobin	115 -160	19/11/2002	1.3	
14/01/2003	Lymphocytes		19/11/2002	0.57	
14/01/2003	Neutrophils	1.8 - 7.5	19/11/2002	0.6	
14/01/2003	White blood cells	4 - 11.0			

Additional Information:

Patient also taking Panadeine forte, Rabeprazole sodium, Temazepam

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181575 **Seq:** 1
Reported: 14/01/2003
Hospitalisation:
Onset Date: 12/11/2002
Outcome: Recovered

Gender: F
Weight: 47.00
Age: 36
DOB: 21/09/1966
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation	Rash on head and neck, fever	
Blood lactate dehydrogenase inc	Caused or prolonged inpatient hospitalisation		
Leukopenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 08/11/2002 **Stopped:** 20/11/2002

Laboratory Investigations:

Additional Information:

Patient also taking Panadeine forte, Rabeprazole sodium, Temazepam

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181575 **Seq:** 1 **Gender:** F
Reported: 14/01/2003 **Weight:** 47.00
Hospitalisation: **Age:** 36
Onset Date: 12/11/2002 **DOB:** 21/09/1966
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation		
Pain	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 08/11/2002 **Stopped:** 20/11/2002

Laboratory Investigations:

Additional Information:

Patient also taking Panadeine forte, Rabeprazole sodium, Temazepam

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181621 **Seq:** 1
Reported: 15/01/2003
Hospitalisation:
Onset Date: 10/12/2002
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 46
DOB: 26/02/1956
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Required Visit to Doctor	Swelling hands; mouth, tongue and lips are burning; tension neck, knees and legs; feeling wobbly, palpitation in the heart	
Hypertonia	Required Visit to Doctor		
Oedema peripheral	Required Visit to Doctor		
Palpitations	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 09/12/2002 **Stopped:** 17/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181643 **Seq:** 1 **Gender:** F
Reported: 15/01/2003 **Weight:** 66.00
Hospitalisation: **Age:** 77
Onset Date: 19/11/2002 **DOB:** 19/01/1925
Outcome: Recovered 27/11/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome	Required Visit to Doctor	Restless legs.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 19/11/2002 **Stopped:** 26/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Cardizem, Fosamax, Avapro and Ducene.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181911 **Seq:** 1 **Gender:** F
Reported: 22/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: 01/11/2002 **DOB:** 07/12/1985
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Chills Diarrhoea Malaise		Nausea, disoder, rigor, malaise	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 12.5 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous reaction to Venlafaxine-anaphylactoid

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181926 **Seq:** 1 **Gender:** F
Reported: 22/01/2003 **Weight:** 75.00
Hospitalisation: **Age:** 39
Onset Date: 25/12/2002 **DOB:** 27/05/1963
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Required Visit to Doctor	Acute onset of pain (arthralgia) begining around m-p joints spreading to shoulders. arthrosis, severe upper limb joint pain, mild hyperaesthesia.	
Arthralgia	Required Visit to Doctor		
Hyperaesthesia	Required Visit to Doctor		
Osteoarthritis	Required Visit to Doctor		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 180.0 Milligram Daily Oral
Batch: **Started:** 20/01/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P.H. low grade rheumatoid arthritis.
Suspected drug positive rechallenge.
Dose of Avanza had been gradually built up in 2002. Patient ceased it rapidly early October 2002 and gradually built dose up to 180mg by December 2002 again.

Report Detail

Case Number: 181935 **Seq:** 1 **Gender:** F
Reported: 22/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 13/10/1950
Outcome: Recovered 04/11/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Polyarthritis	Required Visit to Doctor	Acute polyarthritis; wrists, fingers, elbows	Ceased Avanza

Medicine Details:

SEREPAX (Other drug) **Reason:** Anxiety neurosis
30.0 Milligram Daily
Batch: **Started:** 07/10/2002 **Stopped:**

TRYPTANOL (Other drug) **Reason:** Depression
150.0 Milligram Daily
Batch: **Started:** 10/11/2002 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 09/10/2002 **Stopped:** 01/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181938 **Seq:** 1 **Gender:** F
Reported: 23/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 20/11/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Required Visit to Doctor	Severe diarrhoea and nausea, dry mouth. Symptoms began after the dose was increased on 18/11/02	
Dry mouth	Required Visit to Doctor		
Nausea	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Batch: **Started:** 04/11/2002 **Stopped:** 22/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 181986 **Seq:** 1 **Gender:** F
Reported: 23/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 29/12/2002 **DOB:** 08/09/1972
Outcome: Recovered 13/01/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Oedema of both legs and ankles below	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 09/12/2002 **Stopped:** 28/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 182024 **Seq:** 1 **Gender:** M
Reported: 23/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: 14/11/2002 **DOB:** 17/10/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Seizure	A & E admission and

Medicine Details:

EFEXOR (Other drug) **Reason:** Depression
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 01/10/2002 **Stopped:** CONTIN

AVANZA (Suspected) **Reason:** Specific disorders of sleep
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 05/11/2002 **Stopped:** 14/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Required operation treatment for dislocated shoulder.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182031 **Seq:** 1 **Gender:** F
Reported: 23/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 53
Onset Date: 02/01/2002 **DOB:** 04/11/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchiness on lower limbs.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 45.0 Milligram Oral
Batch: **Started:** 19/11/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Worse as dose of mirtazapine increased to 60mg. Still present at 45mg but tolerable. Absent when medication ceased. Patient also taking Olanzapine, Diazepam, panadeine forte and Vioxx.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182061 **Seq:** 1
Reported: 24/01/2003
Hospitalisation:
Onset Date: 19/12/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 56
DOB: 28/10/1946
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Required Visit to Doctor	Hallucination, mania acute, behaviour abnormal; foul mouth (swearing), insomnia	Stopped medication. Treated with valium
Abnormal behaviour	Required Visit to Doctor		
Agitation	Required Visit to Doctor		
Mania	Required Visit to Doctor		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 19/12/2002 **Stopped:** 22/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182065 **Seq:** 1 **Gender:** F
Reported: 24/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 33Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Increased appetite Weight increased		Appetite increased, weight gain	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 07/10/2002 **Stopped:** 31/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient has been gaining 2-3 kg weekly; cannot get her rings on her fingers. Generally has good diet; exercises.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182152 **Seq:** 1
Reported: 29/01/2003
Hospitalisation:
Onset Date:
Outcome: Recovered with sequelae

Gender: F
Weight: 0.00
Age: 83
DOB: 29/06/1919
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blindness Glaucoma		Blindness, exacerbation of glaucoma. Patient needed surgery to correct glaucoma.	surgery

Medicine Details:

REMERON (Suspected) **Reason:**

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182190 **Seq:** 1 **Gender:** M
Reported: 31/01/2003 **Weight:** 95.00
Hospitalisation: **Age:** 36
Onset Date: 07/01/2003 **DOB:** 15/06/1966
Outcome: Recovered 10/01/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Required Visit to Doctor	Paraesthesiae and muscle twitching.	
Muscle twitching	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Other drug) **Reason:** Unspecified psychosis
30.0 Milligram Daily
Batch: **Started:** 01/01/2001 **Stopped:**

ACIMAX (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 15/11/2002 **Stopped:** 09/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182195 **Seq:** 1
Reported: 31/01/2003
Hospitalisation:
Onset Date: 01/12/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 56
DOB: 28/10/1946
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Severe agitation which lasted two days	Remeron ceased

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 01/12/2002 **Stopped:** 07/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182288 **Seq:** 1 **Gender:** F
Reported: 04/02/2003 **Weight:** 57.00
Hospitalisation: **Age:** 22
Onset Date: 21/01/2003 **DOB:** 11/04/1980
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice	Required Visit to Doctor	Jaundice, Ataxia and peripheral oedema	Ceased Avanza
Coordination abnormal	Required Visit to Doctor		
Oedema peripheral	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 21/01/2003 **Stopped:** 21/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182294 **Seq:** 1 **Gender:** F
Reported: 04/02/2003 **Weight:** 62.00
Hospitalisation: **Age:** 39
Onset Date: **DOB:** 21/12/1963
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anger	Required Visit to Doctor	Rage, irritability, hypersensitivity.	
Hypersensitivity	Required Visit to Doctor		
Irritability	Required Visit to Doctor		

Medicine Details:

LOSEC (Other drug) **Reason:** Other diseases of esophagus
Batch: **Started:** **Stopped:**

EPILIM (Other drug) **Reason:** Headache
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred sometime in December 2002.
Avanza was started sometime in November 2002 and stopped sometime in January 2003.

Patient was also taking Questran, masasal.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182500 **Seq:** 1
Reported: 07/02/2003
Hospitalisation:
Onset Date: 15/12/2002
Outcome: Not yet recovered

Gender: F
Weight: 118.00
Age: 37
DOB: 13/07/1965
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Generalised oedema		Generalised oedema especially legs.	Currently trying lower dose of

Medicine Details:

AROPAX (Other drug) **Reason:**
80.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/09/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182506 **Seq:** 1 **Gender:** M
Reported: 07/02/2003 **Weight:** 80.00
Hospitalisation: **Age:** 96
Onset Date: 06/01/2003 **DOB:** 03/06/1906
Outcome: Recovered 08/01/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state		increasing drowsiness over 3 days with ataxia and confusion, not wanting to eat, wanting to sleep all the time, BP/P/Temp normal	Avanza ceased.
Coordination abnormal		increasing drowsiness over 3 days with ataxia and confusion, not wanting to eat, wanting to sleep all the time, BP/P/Temp normal	Avanza ceased.
Somnolence	Required Visit to Doctor	increasing drowsiness over 3 days with ataxia and confusion, not wanting to eat, wanting to sleep all the time, BP/P/Temp normal	Avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 03/01/2003 **Stopped:** 06/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Coversyl, Timpilo and Zoton.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182510 **Seq:** 1 **Gender:** F
Reported: 07/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 37Y
Onset Date: 18/11/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Skin rash with urticaria	Phenergan 25mg tds, stopped mirtazapine.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 13/11/2002 **Stopped:** 18/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182605 **Seq:** 1
Reported: 10/02/2003
Hospitalisation:
Onset Date: 01/10/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 36Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Fatigue Arthralgia Skin hyperpigmentation Somnolence		Weight gain of 8kg, fluid retention, legs feel heavy at end of day pains in knee	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182630 **Seq:** 1 **Gender:** F
Reported: 10/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 30
Onset Date: 23/01/2003 **DOB:** 28/03/1972
Outcome: Recovered 24/01/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Required Visit to Doctor	Serotonergic syndrome, increasing tremor, dysphoria, headache.	
Headache	Required Visit to Doctor	Serotonergic syndrome, increasing tremor, dysphoria, headache.	
Serotonin syndrome	Required Visit to Doctor	Serotonergic syndrome, increasing tremor, dysphoria, headache.	
Tremor	Required Visit to Doctor	Serotonergic syndrome, increasing tremor, dysphoria, headache.	

Medicine Details:

AVANZA (Interaction) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** Contin

TRAMAL SR (Interaction) **Reason:** Pain
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 18/01/2003 **Stopped:** 23/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Avanza dose started in 2002.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182687 **Seq:** 1
Reported: 11/02/2003
Hospitalisation: Hospitalisation prolonged
Onset Date: 20/01/2003
Outcome: Not yet recovered

Gender: F
Weight: 74.00
Age: 74
DOB: 01/08/1928
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiac failure		Pitting oedema to knees, JVP ~ 8cm.	Frusemide. Elevation of legs.
Gravitational oedema		Pitting oedema to knees, JVP ~ 8cm.	Frusemide. Elevation of legs.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 16/01/2003 **Stopped:** 21/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Tegretol CR, Paxam, Ranitidine and Coloxyl with Senna.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182730 **Seq:** 1
Reported: 11/02/2003
Hospitalisation:
Onset Date: 15/08/2002
Outcome: Not yet recovered

Gender: M
Weight: 130.00
Age: 32
DOB: 12/03/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Required Visit to Doctor	Poly arthralgia in fingers, knees, elbows	Avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 26/07/2002 **Stopped:** 30/08/2002

EPILIM (Suspected) **Reason:** Pain
600.0 Milligram Daily
Batch: **Started:** 10/08/2002 **Stopped:** 30/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Lipitor, Lisinopril and Metformin.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182820 **Seq:** 1 **Gender:** M
Reported: 13/02/2003 **Weight:** 107.00
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 14/01/1950
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia	Required Visit to Doctor	S.O.A and tenderness of feet which subsided when ceased. Occurred with increase from 30mg - 60mg/day	
Oedema peripheral	Required Visit to Doctor	S.O.A and tenderness of feet which subsided when ceased. Occurred with increase from 30mg - 60mg/day	
Paraesthesia	Required Visit to Doctor	S.O.A and tenderness of feet which subsided when ceased. Occurred with increase from 30mg - 60mg/day	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 21/12/2002 **Stopped:** 16/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge. Other drugs - Kinidin Durules, Lanoxin, Normison and Oxycontin.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182873 **Seq:** 1
Reported: 14/02/2003
Hospitalisation:
Onset Date:
Outcome: Death, maybe drug

Gender: M
Weight: 78.00
Age: 81
DOB: 16/02/1921
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic failure		Liver failure, pulmonary hypertension.	
Pulmonary hypertension		Liver failure, pulmonary hypertension.	

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspected)			**Reason:**	Abdominal pain	
Tablet	50.0	Milligram	As necessary		Oral
Batch:	**Started:**			**Stopped:**	25/01/2003
MACRODANTIN (Suspected)			**Reason:**	Othr diseases of urinary tract	
Capsule	100.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	03/02/2003
LASIX (Suspected)			**Reason:**		
Tablet	80.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	25/01/2003
AVANZA (Suspected)			**Reason:**	Depression	
Tablet	45.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	25/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182873 **Seq:** 1
Reported: 14/02/2003
Hospitalisation:
Onset Date:
Outcome: Death, maybe drug

Gender: M
Weight: 78.00
Age: 81
DOB: 16/02/1921
Causality: Causality possible

Reaction Detail

Medicine Details:

TEMAZE (Suspected) **Reason:** Specific disorders of sleep
10.0 Milligram Daily
Batch: **Started:** **Stopped:** 25/01/2003

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182893 **Seq:** 1 **Gender:** M
Reported: 14/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 56
Onset Date: 03/02/2003 **DOB:** 02/02/1947
Outcome: Recovered 07/02/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Severe generalised arthralgia half an hour after dose. Lasted 1 hour, exacerbation reflux sedation 4 days	
Somnolence		Severe generalised arthralgia half an hour after dose. Lasted 1 hour, exacerbation reflux sedation 4 days	

Medicine Details:

PREDNISOLONE (Other drug) **Reason:** Sarcoidosis
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 03/02/2003 **Stopped:** 04/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 182937 **Seq:** 1 **Gender:** F
Reported: 14/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: **DOB:** 07/12/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia	Required Visit to Doctor	Severe restless legs syndrome - also involving her arms	NSAIDS and paracetamol. Ceased Avanza

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 16/09/2002 **Stopped:** 25/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 183173 **Seq:** 1 **Gender:** M
Reported: 24/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 79Y
Onset Date: 14/02/2003 **DOB:**
Outcome: Recovered 15/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disorientation Agitation Hallucination		Disorientation, hallucination, agitation	Cased Mirtazapine

Medicine Details:

TRAMADOL HYDROCHLORIDE (Other drug)			**Reason:**	Pain	
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
FRUSEMIDE (Other drug)			**Reason:**	Congestive heart failure	
Tablet	240.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
MIRTAZAPINE (Suspected)			**Reason:**		
Tablet	15.0	Milligram	Daily		Oral
Batch:	**Started:**	10/02/2003		**Stopped:**	13/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/02/2003	Other data				

Additional Information:

Patient was also taking GTN, Warfarin.
Background CCf.

Report Detail

Case Number: 183644 **Seq:** 1 **Gender:** F
Reported: 03/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 55
Onset Date: 11/02/2003 **DOB:** 04/03/1947
Outcome: Recovered 18/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life	Patient suffered Seizure and Hyponatraemia. Coffee drinker (14 cups) per day	
Hyponatraemia	Life		

Medicine Details:

MIRTAZAPINE (Interaction) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 04/02/2002 **Stopped:** 13/02/2003

CAFFEINE (Interaction) **Reason:**
14.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Temazepam, Diazepam, Omeprazole, Thiamine, Haloperidol and Benztropine.
Smoker: 40+ per day. Coffee: 14 cups per day

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 183718 **Seq:** 1
Reported: 05/03/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: U
Weight: 0.00
Age: 56
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation	Caused or prolonged inpatient hospitalisation	Atrial fibrillation. extrasystoles	
Extrasystoles	Caused or prolonged inpatient hospitalisation		

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

At the time had a normal ECG.
History: Mitral valve prolapse and conduction disorders.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 183761 **Seq:** 1 **Gender:** M
Reported: 06/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 48
Onset Date: 28/02/2003 **DOB:** 12/02/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Required Visit to Doctor	Confusion, drowsiness, slurred speech, disorientation	
Disorientation	Required Visit to Doctor		
Dysarthria	Required Visit to Doctor		
Somnolence	Required Visit to Doctor		

Medicine Details:

AVAPRO HCT 300/12.5 (Other drug) **Reason:** Essential benign hypertension
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ADALAT (Other drug) **Reason:** Essential benign hypertension
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 30.0 Milligram Total Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cipramil was ceased for 48 hours befire starting Avanza.

Report Detail

Case Number: 183765 **Seq:** 1 **Gender:** F
Reported: 06/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 47
Onset Date: 11/11/2002 **DOB:** 27/02/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression	Required Visit to Doctor	Aggression, agitation, suicidal, headaches, nasal congestion and bleeding, palpitations	Panamax,
Agitation	Required Visit to Doctor		
Headache	Required Visit to Doctor		
Nasal congestion	Required Visit to Doctor		
Palpitations	Required Visit to Doctor		

Medicine Details:

CIPRAMIL (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 13/11/2002

AVANZA (Interaction) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 11/11/2002 **Stopped:** 20/11/2002

DUCENE (Other drug) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 183765 **Seq:** 1 **Gender:** F
Reported: 06/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 47
Onset Date: 11/11/2002 **DOB:** 27/02/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Required Visit to Doctor		

Medicine Details:

CIPRAMIL (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 13/11/2002

AVANZA (Interaction) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 11/11/2002 **Stopped:** 20/11/2002

DUCENE (Other drug) **Reason:** Depression
15.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** Contin

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 183858 **Seq:** 1 **Gender:** M
Reported: 10/03/2003 **Weight:** 83.00
Hospitalisation: **Age:** 49
Onset Date: 27/11/2003 **DOB:** 22/03/1954
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Depersonalisation Disorientation Dyskinesia Hallucination Lethargy		Took Avanza at 9pm - couldn't sleep. By 11pm jerking and tossing. Next morning disoriented, lethargic and felt mind outside body at work. 11am black shape jerking up and down in vision, like movie about to break.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 27/02/2003 **Stopped:** 28/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

He felt pre-epileptic.
Was OK on Zoloft in past.

Report Detail

Case Number: 184004 **Seq:** 1
Reported: 13/03/2003
Hospitalisation:
Onset Date: 08/03/2003
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 38
DOB: 25/03/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hiccups Hyperhidrosis Reflux oesophagitis		Hiccoughing, increased sweating, reflux	

Medicine Details:

AVANZA (Interaction) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TRAMAL (Interaction) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 08/03/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184037 **Seq:** 1 **Gender:** M
Reported: 14/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 90Y
Onset Date: 14/11/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia.	

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:**
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 18/11/2002

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 22/10/2002 **Stopped:** 28/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/03/2003	Neutrophils		07/11/2002	2.0	
14/03/2003	Neutrophils		14/11/2002	1.5	
14/03/2003	Neutrophils		29/11/2002	1.2	
14/03/2003	Neutrophils		03/12/2002	1.2	
14/03/2003	Neutrophils		06/12/2002	1.3	
14/03/2003	Neutrophils		10/12/2002	1.5	
14/03/2003	White blood cells		07/11/2002	5.3	

Additional Information:

Neutropaenia unknown origin.
Had previous investigation for myelodysplasia in July 2002.

Report Detail

Case Number: 184037 **Seq:** 1 **Gender:** M
Reported: 14/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 90Y
Onset Date: 14/11/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

LITHIUM CARBONATE (Other drug)			**Reason:**		
Tablet	250.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	18/11/2002
MIRTAZAPINE (Suspected)			**Reason:**	Depression	
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**	22/10/2002		**Stopped:**	28/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/03/2003	White blood cells		06/12/2002	3.3	
14/03/2003	White blood cells		10/12/2002	3.7	

Additional Information:

Neutropaenia unknown origin.
Had previous investigation for myelodysplasia in July 2002.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184125 **Seq:** 1 **Gender:** F
Reported: 19/03/2003 **Weight:** 65.00
Hospitalisation: **Age:** 20
Onset Date: 15/03/2003 **DOB:** 11/08/1982
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erythema	Required Visit to Doctor	Erythematous rash covering face, neck and chest, small papules present, non-itchy.	Hydrocortisone cream.
Rash papular	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 10/03/2003 **Stopped:** 15/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mild rash developed after 2 days treatment, patient ceased drug but restarted after 2 days. Rash exacerbated with rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184208 **Seq:** 1
Reported: 20/03/2003
Hospitalisation: Admitted to hospital
Onset Date: 25/02/2003
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 85
DOB: 02/05/1917
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope Convulsion Dysphasia Movement disorder Orthostatic hypotension		Syncope, postural hypotension, convulsive episode, expressive dysphasis, chorieform movements.	Given Midazolam and

Medicine Details:

AVANZA (Suspected)			**Reason:**	Depression	
Tablet	60.0	Milligram	As necessary		Oral
Batch:	**Started:**			**Stopped:**	
SEROQUEL (Suspected)			**Reason:**	Depression	
Tablet	150.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
EFEXOR-XR (Suspected)			**Reason:**	Depression	
Tablet	75.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 184232 **Seq:** 1 **Gender:** F
Reported: 21/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 48
Onset Date: 03/03/2003 **DOB:** 07/10/1954
Outcome: Recovered 10/03/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Required Visit to Doctor	Neutropenia	

Medicine Details:

VALIUM (Other drug) **Reason:** Anxiety neurosis
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184441 **Seq:** 1
Reported: 27/03/2003
Hospitalisation:
Onset Date: 11/03/2003
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 21
DOB: 19/07/1981
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hot flush	Required Visit to Doctor	Hot flushes occurring every 1/2 hour.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 04/03/2003 **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

25/3/2003 - Flushes now occuring less frequently (4 or 5 times a day).

Report Detail

Case Number: 184446 **Seq:** 1 **Gender:** M
Reported: 27/03/2003 **Weight:** 65.00
Hospitalisation: **Age:** 20
Onset Date: 07/02/2003 **DOB:** 15/12/1982
Outcome: Recovered 10/02/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Epileptic convulsion.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 45.0 Milligram Daily Oral

Batch: **Started:** 13/01/2003 **Stopped:** 07/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: PTSD, used marijuana.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184562 **Seq:** 1 **Gender:** M
Reported: 02/04/2003 **Weight:** 100.00
Hospitalisation: **Age:** 49
Onset Date: 20/03/2003 **DOB:** 20/02/1954
Outcome: Recovered 23/03/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor	Nausea followed by muscle control loss and mood swings.	
Mood swings	Required Visit to Doctor		
Muscle disorder	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Stilnox, Neurontin, Zyloprim and Indocid.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184581 **Seq:** 1 **Gender:** F
Reported: 02/04/2003 **Weight:** 71.00
Hospitalisation: **Age:** 86
Onset Date: 21/02/2003 **DOB:** 28/11/1916
Outcome: Recovered 05/03/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Inappropriate antidiuretic hormon		Patient developed hyponatraemia due to ADH following use of Mirtazapine.	

Medicine Details:

AVANZA (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** 17/02/2003 **Stopped:** 24/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2003	Other data	0.1 - 7.0			
02/04/2003	Sodium	135 - 149mmol/L	04/02/2003	135	
02/04/2003	Sodium	135 - 149mmol/L	21/02/2003	130	
02/04/2003	Sodium	135 - 149mmol/L	05/03/2003	134	
02/04/2003	Urine Sodium		21/02/2003	42	
02/04/2003	Urine Sodium		05/03/2003	27	
02/04/2003	Urine osmolality	50 -	21/02/2003	398	

Additional Information:

Patient also taking Amiodarone, Diamicron, Oroxine, Avapro, Cartia, Fosamax, Losec, Lipitor and Stilnox.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184581 **Seq:** 1 **Gender:** F
Reported: 02/04/2003 **Weight:** 71.00
Hospitalisation: **Age:** 86
Onset Date: 21/02/2003 **DOB:** 28/11/1916
Outcome: Recovered 05/03/2003 **Causality:** Causality probable

Reaction Detai

Medicine Details:

AVANZA (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** 17/02/2003 **Stopped:** 24/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2003	Urine osmolality	50 -	05/03/2003	419	

Additional Information:

Patient also taking Amiodarone, Diamicron, Oroxine, Avapro, Cartia, Fosamax, Losec, Lipitor and Stilnox.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184876 **Seq:** 1 **Gender:** F
Reported: 10/04/2003 **Weight:** 52.00
Hospitalisation: **Age:** 56
Onset Date: 20/03/2003 **DOB:** 28/09/1946
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare Agitation Condition aggravated Feeling abnormal		Nightmare, aggravation in continence and agitated, "felt dreadful".	

Medicine Details:

VIOXX (Other drug) **Reason:** Pain
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** Contin

AVANZA (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to Pethidein - rash.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184921 **Seq:** 1 **Gender:** F
Reported: 11/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: 26/03/2003 **DOB:** 21/11/1951
Outcome: Recovered 28/03/2003 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restlessness	Severe	A severe increase in symptoms and	Ceased Avanza

Medicine Details:

AVANZA (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

After first dose of Avanza had symptoms and same reaction after 2nd dose.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184969 **Seq:** 1
Reported: 15/04/2003
Hospitalisation:
Onset Date: 01/01/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 49
DOB: 13/09/1953
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Polyarthritis	Required Visit to Doctor	Severe polyarthritis with dose escalaticis	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 37.5 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient may need hospitalisation if symptoms do not improve.
Patient developed polyarthralgia after a dose increment soon after starting Avanza and this settled with dose reduction and then recurred when the dose was increased again.

Report Detail

Case Number: 184978 **Seq:** 1 **Gender:** M
Reported: 14/04/2003 **Weight:** 60.00
Hospitalisation: **Age:** 83
Onset Date: 11/03/2003 **DOB:** 12/07/1919
Outcome: Recovered 04/04/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Required Visit to Doctor	Postural Hypotension.	

Medicine Details:

QUETIAPINE (Other drug) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

TEMAZEPAM (Other drug) **Reason:**
Oral application Dose Unspecified Oral
Batch: **Started:** **Stopped:**

OXAZEPAM (Other drug) **Reason:**
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 06/03/2003 **Stopped:** 31/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/04/2003	LDH				

Additional Information:

History: Dementia.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 184990 **Seq:** 1 **Gender:** F
Reported: 11/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 15/03/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tic		Developed head Tic within fortnight of commencing Mirtazapine.	

Medicine Details:

MIRTAZAPINE (Interaction) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TRAMAL (Interaction) **Reason:** Otr&unsp vertebrogen pain synd
800.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had been on high dose of Nefazodone prior to Mirtazapine. Dose start and stop dates early 03/03 to late 03/03.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185021 **Seq:** 1
Reported: 14/04/2003
Hospitalisation:
Onset Date: 07/04/2003
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 78
DOB: 29/08/1924
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	Ankle oedema.	Withdrew Mirtazapine

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Anxiety neurosis
1.0 Dose Unspecified Daily
Batch: **Started:** 01/04/2003 **Stopped:** 07/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185121 **Seq:** 1 **Gender:** M
Reported: 17/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 03/03/2003 **DOB:**
Outcome: Recovered 15/03/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain in extremity Oedema peripheral		Sore and painful feet, leg oedema	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/03/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Temaze, Codalgin Forte, Celebrex and Panamax.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185268 **Seq:** 1
Reported: 28/04/2003
Hospitalisation: Admitted to hospital
Onset Date: 15/04/2002
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 47
DOB: 09/07/1954
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder	Severe	Obsessive-compulsive disorder	Given Clomipramine and

Medicine Details:

REMERON (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** 01/02/2002 **Stopped:** 22/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Obsessive symtopms had not been evident on prior antidepressants. History of recurrent major depressive episodes and panic disorder.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185328 **Seq:** 1
Reported: 01/05/2003
Hospitalisation:
Onset Date: 11/12/2002
Outcome: Not yet recovered

Gender: U
Weight: 0.00
Age: 92
DOB: 13/02/1910
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Joint swelling		Swollen ankles and lower legs	Mirtazapine ceased.
Oedema peripheral		Swollen ankles and lower legs	Mirtazapine ceased.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 05/11/2002 **Stopped:** 14/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Erocalciferol, Coloxyl with senna, Lactulose, Microlax, Clotrimazole, paracetamol, Tears natural.
No english.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185365 **Seq:** 1 **Gender:** M
Reported: 28/04/2003 **Weight:** 64.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 27/02/2003 **DOB:** 23/11/1973
Outcome: Recovered 27/02/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Generalised tonic-clonic seizure	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 10/02/2003 **Stopped:** 27/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No risk factors for epilepsy. Started Mirtazapine at 15mg/daily and increased to 30mg/daily after one week.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185391 **Seq:** 1
Reported: 04/05/2003
Hospitalisation:
Onset Date: 29/06/2002
Outcome: Recovered without treatment

Gender: F
Weight: 58.00
Age: 23
DOB: 03/12/1978
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Severe	Moments of schizophrenia followed by suicidal thoughts.	
Agitation	Severe	Pyschiatric agitation/restlessness/dis-belief	
Depersonalisation	Severe	Withdrawal from "normal" social routines and sense of involvement. Total loss of sense of self	
Restlessness	Severe		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Batch: **Started:** 28/06/2002 **Stopped:** 15/08/2002

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule Oral
Batch: **Started:** 28/03/2002 **Stopped:** 28/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185397 **Seq:** 1 **Gender:** F
Reported: 29/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 76Y
Onset Date: 17/02/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotension Fall		Bromocriptine - led to patient becoming hypotensive - causing fall and possibly a broken left hip	Ceased bromocriptine, reduced madopar dose by half. Halved mirtazipine dose.

Medicine Details:

BROMOCRIPTINE MESYLATE (Suspected) **Reason:** Paralysis agitans
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 04/10/2002 **Stopped:** 17/02/2003

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 04/10/2002 **Stopped:**

MADOPAR (Suspected) **Reason:** Paralysis agitans
Tablet 5.0 Dose Unspecified Daily Oral
Batch: **Started:** 17/01/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Docusate-senna, paracetamol, Olanzapine, pantoprazole.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185660 **Seq:** 1 **Gender:** F
Reported: 08/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 47
Onset Date: 01/01/2003 **DOB:** 24/12/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Back pain		Weight increase and fluid retention.	
Fluid retention		Weight increase and fluid retention.	
Weight increased		Weight increase and fluid retention.	Mirtazapine, Valproate and Clonidine ceased and alternative analgesia trialled during hospital admission. Frusemide was initiated to improve urine output and remove excess fluid.

Medicine Details:

AVANZA (Suspected) **Reason:** Pain
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:**
Tablet 800.0 Mole Daily Oral
Batch: **Started:** **Stopped:**

CLONIDINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 400.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Naproxen, Promethazine, Oxycodone and Temazepam.
Patient demonstrated a weight gain from 55kg to 75kg in the previous 2 months.
Patient has history of haematuria loin pain syndrome and was admitted with persistent, severe right loin pain.

Report Detail

Case Number: 185847 **Seq:** 1 **Gender:** F
Reported: 13/05/2003 **Weight:** 83.00
Hospitalisation: **Age:** 56
Onset Date: 15/06/2002 **DOB:** 12/11/1945
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysphagia		Difficulty in swallowing, tightness and aching in shoulder girdle and forearm muscles	
Myalgia		Difficulty in swallowing, tightness and aching in shoulder girdle and forearm muscles	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Serepax, Ogen, Micardis, Celebrex.
Reaction occurred sometime in June 2002.
Avanza was started sometime in September 2001 and stopped sometime in February 2003.

Pain more evidient after increase in Avanza to 60mg.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185916 **Seq:** 1 **Gender:** F
Reported: 15/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed		Changed from Avanza to Mirtazon	
Dizziness		Dizziness, confusional episodes, blurred vision	
Mydriasis		Widely dilated pupils, ataxia, numbness and loss of taste	
Ageusia			
Confusional state			
Coordination abnormal			
Hypoaesthesia			
Vision blurred			

Medicine Details:

Mirtazon (Suspected) **Reason:**

Oral application 45.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On changing back to Avanza, within two days she noted that the symptoms were improving and had almost completely resolved within a week.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185968 **Seq:** 1 **Gender:** F
Reported: 15/05/2003 **Weight:** 64.00
Hospitalisation: **Age:** 35Y
Onset Date: 20/03/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Flight of ideas (mild only) florid behaviour active ++ increased spending - poor sleep.	
Hypomania		Hypomanic, suicidal thoughts, confusion, poor sleep.	Given Duagepam for agitation.
Confusional state			
Suicidal ideation			

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 28/01/2003 **Stopped:** 28/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: longterm anxiety disorder and major depression disorder. PTSD from abuse.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 185999 **Seq:** 1 **Gender:** U
Reported: 15/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness	Required Visit to Doctor	Passed out	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 28/04/2003 **Stopped:** 28/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No past exposure. Allergy to Codeine. Other drugs: Amoxyl, Aspirin, Felodur ER, Metformin, Perindopril, Simvastatin, Insulin and Losec.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186091 **Seq:** 1 **Gender:** F
Reported: 20/05/2003 **Weight:** 58.00
Hospitalisation: **Age:** 47
Onset Date: 06/05/2003 **DOB:** 02/11/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Required Visit to Doctor	Rash.	Nil.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 07/03/2003 **Stopped:** 07/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This is the 3rd patient I have seen with a rash from Avanza.

Report Detail

Case Number: 186092 **Seq:** 1 **Gender:** F
Reported: 20/05/2003 **Weight:** 75.00
Hospitalisation: **Age:** 46
Onset Date: 08/04/2003 **DOB:** 14/11/1956
Outcome: Recovered 01/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Required Visit to Doctor	Arthralgia and mylargia.	Nil.
Myalgia	Required Visit to Doctor	Arthralgia and mylargia.	

Medicine Details:

SANDOMIGRAN (Other drug) **Reason:** Migraine
Tablet 0.2 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 07/04/2003 **Stopped:** 09/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186130 **Seq:** 1 **Gender:** F
Reported: 21/05/2003 **Weight:** 75.00
Hospitalisation: **Age:** 74
Onset Date: 14/05/2003 **DOB:** 03/07/1928
Outcome: Recovered 16/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue	Severe	Severe nightmares-very frightening,	
Nightmare	Severe	Severe nightmares-very frightening,	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram 1 time Oral

Batch: **Started:** 14/05/2003 **Stopped:** 14/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Astrix, Quinine, Iscover, Lipitor, Losec, N/L spray, Panamax, Norvasc, Noten. Mobic.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186199 **Seq:** 1 **Gender:** M
Reported: 26/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	Collapse, dramatic drop in platelets, diarrhoea, very low temperature	Rendered unconscious and needed respiratory assistance. Mirtazapine and Olanazapine ceased.
Body temperature decreased	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186199 **Seq:** 1 **Gender:** M
Reported: 26/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 186207 **Seq:** 1
Reported: 26/05/2003
Hospitalisation:
Onset Date: 03/03/2003
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 89Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle contractions involuntary		Fasciculations bilaterally in arms and legs	Monitor closely by GP on

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 27/02/2003 **Stopped:** contin

SODIUM VALPROATE (Suspected) **Reason:** Convulsions
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 28/02/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was Temazepam, Vitamins-Multi-Vitamin, Aspirin, Salbutamol, Fluticasone.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186400 **Seq:** 1
Reported: 30/05/2003
Hospitalisation:
Onset Date: 25/07/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 32
DOB: 30/03/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Severe hallucinations (I saw a red rifle pointed at me through the window and I turned and smashed my left eye into our bed side table corner) and extremely drowsy.	
Hallucination	Severe	Severe hallucinations (I saw a red rifle pointed at me through the window and I turned and smashed my left eye into our bed side table corner) and extremely drowsy.	

Medicine Details:

PANADOL (Other drug) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet Dose Unspecified Daily Oral
Batch: **Started:** 05/05/2002 **Stopped:** 01/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had 3 stitches next day to my eye.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186402 **Seq:** 1
Reported: 30/05/2003
Hospitalisation:
Onset Date: 22/05/2003
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 50
DOB: 21/01/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Hallucinations, nightmares, headaches, paraesthesia, agitation	
Hallucination	Required Visit to Doctor	Hallucinations, nightmares, headaches, paraesthesia, agitation	
Headache	Required Visit to Doctor	Hallucinations, nightmares, headaches, paraesthesia, agitation	
Nightmare	Required Visit to Doctor	Hallucinations, nightmares, headaches, paraesthesia, agitation	
Paraesthesia	Required Visit to Doctor	Hallucinations, nightmares, headaches, paraesthesia, agitation	

Medicine Details:

PREMARIN (Other drug) **Reason:** Menopausal symptoms
Tablet — Dose Unspecified — Daily — Oral
Batch: **Started:** **Stopped:**

AROPAX (Other drug) **Reason:** Depression
Oral application — 40.0 Milligram — Daily — Oral
Batch: **Started:** **Stopped:** 20/05/2003

AVANZA (Suspected) **Reason:** Depression
Tablet — 30.0 Milligram — Daily — Oral
Batch: **Started:** 21/05/2003 **Stopped:** 28/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186412 **Seq:** 1 **Gender:** F
Reported: 30/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 05/10/1954
Outcome: Recovered 04/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	Sore throat, oedema of ankles	Onset for ankle oedema -
Pharyngolaryngeal pain	Required Visit to Doctor	Sore throat, oedema of ankles	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 20/03/2003 **Stopped:** 02/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186429 **Seq:** 1 **Gender:** F
Reported: 30/05/2003 **Weight:** 67.00
Hospitalisation: **Age:** 59
Onset Date: 01/03/2003 **DOB:** 09/08/1943
Outcome: Recovered 10/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema		Elevated oedema in legs	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Astrix, Biquinate, Cardizem and Mono Plus.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186559 **Seq:** 1 **Gender:** F
Reported: 03/06/2003 **Weight:** 94.00
Hospitalisation: **Age:** 44
Onset Date: 15/04/2003 **DOB:** 02/05/1958
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthma	Required Visit to Doctor	Exacerbation of asthma	Ceased Avanza

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Possible exacerbation of asthma.
Patient was also taking Pulmicort, Serevent, Ventolin.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186570 **Seq:** 1 **Gender:** F
Reported: 03/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 45
Onset Date: 15/03/2003 **DOB:** 01/10/1957
Outcome: Recovered 19/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Required Visit to Doctor	Elevated liver enzyme	Ceased Avanza

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 07/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Avanza was started sometime in march 2003.
Reaction occurred sometime in march 2003.
patient was also taking Amisulpride, Antenex, Epilim, Metformin, Thiamine. Grossly elevated LFT's

Report Detail

Case Number: 186610 **Seq:** 1
Reported: 05/06/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 82
DOB: 03/10/1920
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams		Vivid dreams (Unpleasant)	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 186615 **Seq:** 1 **Gender:** M
Reported: 05/06/2003 **Weight:** 100.00
Hospitalisation: **Age:** 53
Onset Date: 06/05/2003 **DOB:** 08/10/1949
Outcome: Recovered 09/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression	Required Visit to Doctor	Aggression, irritability, poor memory, impaired cognition - moderate - severe.	
Irritability	Required Visit to Doctor	Aggression, irritability, poor memory, impaired cognition - moderate - severe.	
Memory impairment	Required Visit to Doctor	Aggression, irritability, poor memory, impaired cognition - moderate - severe.	

Medicine Details:

FELDENE (Other drug) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 31/03/2003 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 06/05/2003 **Stopped:** 08/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186712 **Seq:** 1 **Gender:** M
Reported: 06/06/2003 **Weight:** 90.00
Hospitalisation: **Age:** 44
Onset Date: 23/04/2003 **DOB:** 09/09/1958
Outcome: Recovered 27/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Diffuse myalgia dose related mainly in legs, some in arms.	Ceased Mirtazapine.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** 16/04/2003 **Stopped:** 26/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186757 **Seq:** 1 **Gender:** M
Reported: 10/06/2003 **Weight:** 70.00
Hospitalisation: **Age:** 26
Onset Date: 31/05/2003 **DOB:** 24/04/1977
Outcome: Recovered 03/03/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Balance disorder	Required Visit to Doctor	Nausea, cold sweat, shaking, loss of balance, vomiting.	
Cold sweat		Nausea, cold sweat, shaking, loss of balance, vomiting.	
Nausea		Nausea, cold sweat, shaking, loss of balance, vomiting.	
Tremor		Nausea, cold sweat, shaking, loss of balance, vomiting.	
Vomiting		Nausea, cold sweat, shaking, loss of balance, vomiting.	

Medicine Details:

Mirtazon (Suspected) **Reason:**
1 time
Batch: **Started:** 31/05/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stopped Mirtazon and returned to Prozac.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186784 **Seq:** 1 **Gender:** M
Reported: 10/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: 10/04/2003 **DOB:** 08/10/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Drowsiness, difficulty walking, diaphorsis, numb hands and feet, some shakes.	Ceased Mirtazepine
Hyperhidrosis		Drowsiness, difficulty walking, diaphorsis, numb hands and feet, some shakes.	Ceased Mirtazepine
Hypoaesthesia		Drowsiness, difficulty walking, diaphorsis, numb hands and feet, some shakes.	Ceased Mirtazepine
Somnolence		Drowsiness, difficulty walking, diaphorsis, numb hands and feet, some shakes.	Ceased Mirtazepine
Tremor		Drowsiness, difficulty walking, diaphorsis, numb hands and feet, some shakes.	Ceased Mirtazepine

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 09/04/2003 **Stopped:** 10/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 186975 **Seq:** 1 **Gender:** F
Reported: 16/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 07/06/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms	Required Visit to Doctor	Patient developed restless legs and	
Restless legs syndrome	Required Visit to Doctor	Patient developed restless legs and	Medication changed.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 04/05/2003 **Stopped:** 10/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 187080 **Seq:** 1
Reported: 11/06/2003
Hospitalisation:
Onset Date: 01/12/2002
Outcome: Recovered with sequelae

Gender: F
Weight: 60.00
Age: 48Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Severe	Thrombocytopaenia, Neutropaenia, Fever, Malaise, Nausea, Lethargy, Numbness/swelling of tongue, Difficulting speaking	
Dysarthria	Severe		
Hypoaesthesia oral	Severe		
Lethargy	Severe		
Malaise	Severe		
Nausea	Severe		
Pyrexia	Severe		
Swollen tongue	Severe		
Thrombocytopenia	Severe		

Medicine Details:

VALIUM (Other drug) **Reason:**
Tablet 5.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

PANADOL (Other drug) **Reason:**
Capsule 1.0 Gram As necessary Oral
Batch: **Started:** **Stopped:**

NEURONTIN (Other drug) **Reason:**
Capsule 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Avanza (mirtazapine) ceased after four doses of taking half a tablet per night at some time during December 2002. Symptoms resolved gradually over a period of about two weeks. Patient had been inadvertantly provided a sample pack of Avanza again recently (6/2003) with repeated symptomatology after one dosage before pharmacist realised that the patient had taken Avanza with serious consequences previously - can be considered a "rechallenge" - unfortunately, no blood tests performed upon second exposure to Avanza. Usage of Neurontin (gabapentin) remained consistent throughout (has been taking Neurontin since about year 2000). Usage of Valium and Panadol are sporadic and only when required.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 187106 **Seq:** 1 **Gender:** F
Reported: 03/05/2003 **Weight:** 110.00
Hospitalisation: **Age:** 39
Onset Date: 28/10/2002 **DOB:** 30/12/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue	Severe	Tiredness, loss of energy, dizziness,depression, anger and the feeling of sucide which still cant get rid of.	
Amnesia	Severe	loss of memory, weight gain, extreme joint pains, swelling of ankles, paranoia,mood change	taken of medication and put on
Anger	Severe		
Arthralgia	Severe		
Asthenia	Severe		
Depression	Severe		
Dizziness	Severe		
Joint swelling	Severe		

Medicine Details:

Mirtazon (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** 28/10/2002 **Stopped:** 27/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 187106 **Seq:** 1 **Gender:** F
Reported: 03/05/2003 **Weight:** 110.00
Hospitalisation: **Age:** 39
Onset Date: 28/10/2002 **DOB:** 30/12/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mood altered	Severe		
Paranoia	Severe		
Suicidal ideation	Severe		
Weight increased	Severe		

Medicine Details:

Mirtazon (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 28/10/2002 **Stopped:** 27/02/2003

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 187615 **Seq:** 1
Reported: 25/06/2003
Hospitalisation:
Onset Date: 04/06/2003
Outcome: Not yet recovered

Gender: M
Weight: 66.00
Age: 19
DOB: 15/07/1983
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photophobia		Increased visual sensitivity to light or glare particulary noticeable when driving through areas of alternating light and shadow.	
Visual disturbance		Increased visual sensitivity to light or glare particulary noticeable when driving through areas of alternating light and shadow.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Anxiety neurosis

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 02/06/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 187666 **Seq:** 1 **Gender:** F
Reported: 25/06/2003 **Weight:** 81.00
Hospitalisation: **Age:** 43
Onset Date: 31/05/2003 **DOB:** 16/08/1959
Outcome: Recovered 02/06/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Hallucination		Confusion and hallucinations, "speaking to people who are not there".	

Medicine Details:

Mirtazon (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 31/05/2003 **Stopped:** 01/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Cipramil, Pariet, Ventolin nebs and Seretide.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 188269 **Seq:** 1 **Gender:** M
Reported: 11/07/2003 **Weight:** 83.00
Hospitalisation: **Age:** 74
Onset Date: 10/07/2003 **DOB:** 11/04/1929
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Serotonin syndrome:- Agitation, Disorientation, Hypertension (BP 210/93)	Stopped Amitriptyline. ? Parkinson's disease. Stop Haloperidol and Metaclopramide
Coordination abnormal	Caused or prolonged inpatient hospitalisation	Unsteadiness and Dizziness, Tremor and ataxia	
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet 12.5 Milligram 1 time Oral
Batch: **Started:** 04/06/2003 **Stopped:** 11/07/2003 0

MIRTAZAPINE (Interaction) **Reason:**
Tablet 45.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

PARACETAMOL (Other drug) **Reason:**
Tablet 1.0 Gram 4 times Oral
Batch: **Started:** 04/06/2003 **Stopped:**

METOCLOPRAMIDE HYDROCHLORIDE (Other drug) **Reason:**
Tablet 10.0 Milligram 3 times Oral
Batch: **Started:** 04/06/2003 **Stopped:** 11/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 188269 **Seq:** 1 **Gender:** M
Reported: 11/07/2003 **Weight:** 83.00
Hospitalisation: **Age:** 74
Onset Date: 10/07/2003 **DOB:** 11/04/1929
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disorientation	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		
Hypertension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

HALOPERIDOL (Other drug) **Reason:**
Tablet 500.0 Microgram 2 times Oral
Batch: **Started:** 03/06/2003 **Stopped:** 10/07/2003

FENTANYL TRANSDERMAL (Other drug) **Reason:**
Patch, dermal 50.0 Microgram Per hour Transdermal
Batch: **Started:** 06/06/2003 **Stopped:**

KETAMINE HYDROCHLORIDE (Other drug) **Reason:**
Injection 150.0 Milligram Daily Subcutaneous
Batch: **Started:** 06/06/2003 **Stopped:** 11/07/2003

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 188269 **Seq:** 1 **Gender:** M
Reported: 11/07/2003 **Weight:** 83.00
Hospitalisation: **Age:** 74
Onset Date: 10/07/2003 **DOB:** 11/04/1929
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet 12.5 Milligram 1 time Oral
Batch: **Started:** 04/06/2003 **Stopped:** 11/07/2003 0

MIRTAZAPINE (Interaction) **Reason:**
Tablet 45.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

PARACETAMOL (Other drug) **Reason:**
Tablet 1.0 Gram 4 times Oral
Batch: **Started:** 04/06/2003 **Stopped:**

METOCLOPRAMIDE HYDROCHLORIDE (Other drug) **Reason:**
Tablet 10.0 Milligram 3 times Oral
Batch: **Started:** 04/06/2003 **Stopped:** 11/07/2003

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 188269 **Seq:** 1
Reported: 11/07/2003
Hospitalisation:
Onset Date: 10/07/2003
Outcome: Unknown

Gender: M
Weight: 83.00
Age: 74
DOB: 11/04/1929
Causality: Causality possible

Reaction Detail

Medicine Details:

HALOPERIDOL (Other drug)			**Reason:**		
Tablet	500.0	Microgram	2 times		Oral
Batch:	**Started:**	03/06/2003		**Stopped:**	10/07/2003
FENTANYL TRANSDERMAL (Other drug)			**Reason:**		
Patch, dermal	50.0	Microgram	Per hour		Transdermal
Batch:	**Started:**	06/06/2003		**Stopped:**	
KETAMINE HYDROCHLORIDE (Other drug)			**Reason:**		
Injection	150.0	Milligram	Daily		Subcutaneous
Batch:	**Started:**	06/06/2003		**Stopped:**	11/07/2003

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 188325 **Seq:** 1 **Gender:** F
Reported: 10/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Required Visit to Doctor	Dizziness, postural hypotention, muscle pain, bloating and increased appetite.	
Abdominal distension	Required Visit to Doctor		
Increased appetite	Required Visit to Doctor		
Myalgia	Required Visit to Doctor		
Orthostatic hypotension	Required Visit to Doctor		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms resolved except muscle pain - still present 02/07/03.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 188332 **Seq:** 1 **Gender:** F
Reported: 07/07/2003 **Weight:** 72.00
Hospitalisation: **Age:** 53
Onset Date: 24/06/2003 **DOB:** 22/08/1949
Outcome: Recovered 30/06/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Required Visit to Doctor	Widespread arthralgia and myalgia especially shoulders and arms.	
Myalgia		Widespread arthralgia and myalgia especially shoulders and arms.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 22/06/2003 **Stopped:** 28/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 188340 **Seq:** 1 **Gender:** F
Reported: 10/07/2003 **Weight:** 65.00
Hospitalisation: **Age:** 49Y
Onset Date: 17/05/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Aggression Hallucination		Agitation, hallucinations, aggression	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 15/05/2003 **Stopped:** 17/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past history of reaction of similar nature to Efexor.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 188847 **Seq:** 1
Reported: 25/07/2003
Hospitalisation:
Onset Date: 18/07/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 22
DOB: 20/04/1981
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Akinesia Dizziness Irritability Nightmare Polyuria Restlessness		Sweating, restlessness, irritability, polyuria, nightmares.	Ceased Avanza.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 15/07/2003 **Stopped:** 21/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Avanza began for depression accompaning withdrawal from substance abuse (speed/THC).
Patient was also taking Tramal and Antenex.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 188973 **Seq:** 1 **Gender:** M
Reported: 01/08/2003 **Weight:** 82.00
Hospitalisation: **Age:** 39
Onset Date: **DOB:** 08/09/1963
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erythema	Required Visit to Doctor	Raised erythema palms of hands and groin with new numbness of already injured left arm.	
Hypoaesthesia	Required Visit to Doctor		
Rash	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 0.5 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Rivotril, Diazepam and Citaloprim.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 189125 **Seq:** 1
Reported: 31/07/2003
Hospitalisation:
Onset Date: 23/07/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 48Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Clumsiness	Required Visit to Doctor	Bumping into things.	
Disorientation	Required Visit to Doctor	During day felt dopey and disoriented, felt like whole body was running on adrenaline and jittery.	
Anxiety	Required Visit to Doctor	Felt like exaggerated anxiety.	
Amnesia	Required Visit to Doctor	Forgetful	
Thinking abnormal	Required Visit to Doctor	Not thinking straight.	

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 23/07/2003 **Stopped:** 24/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 189125 **Seq:** 1
Reported: 31/07/2003
Hospitalisation:
Onset Date: 23/07/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 48Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome	Required Visit to Doctor	Took Avanza (1/2 x 30mg) and had restless legs all night.	Ceased Avanza

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 23/07/2003 **Stopped:** 24/07/2003

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 189192 **Seq:** 1 **Gender:** M
Reported: 06/08/2003 **Weight:** 70.00
Hospitalisation: **Age:** 27
Onset Date: 20/07/2003 **DOB:** 20/03/1976
Outcome: Recovered 24/07/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mydriasis	Required Visit to Doctor	Mydriasis	

Medicine Details:

EFEXOR-XR (Suspected) **Reason:** Phobic neurosis
75.0 Milligram Daily
Batch: **Started:** 15/07/2003 **Stopped:** 21/07/2003

AVANZA (Suspected) **Reason:** Anxiety neurosis
30.0 Milligram Daily
Batch: **Started:** 10/07/2003 **Stopped:** 21/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prior therapy with efexor year ago "felt strange" and discontinued.

Report Detail

Case Number: 189316 **Seq:** 1 **Gender:** F
Reported: 06/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 85Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 31/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 189508 **Seq:** 1
Reported: 14/08/2003
Hospitalisation:
Onset Date: 30/06/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 55
DOB: 18/01/1948
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cellulitis	Caused or prolonged inpatient hospitalisation	Cellulitis of leg, methicillin-resistant staphylococcal aureus infection and edema lower limb.	
Bacterial infection	Caused or prolonged inpatient hospitalisation		
Oedema peripheral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMODAL (Suspected) **Reason:** Malig n otr prts nerv syst nos
Capsule 320.0 Milligram 4 times Oral
Batch: **Started:** 18/06/2003 **Stopped:** 22/06/2003

DEXAMETHASONE (Suspected) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 03/06/2003 **Stopped:** Contin

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:** Convulsions
Tablet 800.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 189547 **Seq:** 1 **Gender:** M
Reported: 14/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 72Y
Onset Date: 06/08/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bone marrow failure		Bone marrow suppression - not	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** 24/07/2003 **Stopped:** 06/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/08/2003	Haemoglobin		08/08/2003	13.7	
14/08/2003	Lymphocytes		08/08/2003	0.4	
14/08/2003	Neutrophils		08/08/2003	1.6	
14/08/2003	Platelets		08/08/2003	96	
14/08/2003	White blood cells		08/08/2003	2.6	

Additional Information:

Other medication taken: Diazepa, Serenace, Panadeine.
Blood count improving.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 189627 **Seq:** 1 **Gender:** F
Reported: 18/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 67
Onset Date: 08/07/2003 **DOB:** 13/11/1935
Outcome: Recovered 09/07/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome Insomnia		Patient felt intense restless legs - she said she "wanted to rip them off", couldn't sleep.	

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 30.0 Milligram 1 time Oral
Batch: **Started:** 08/07/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Cartia, Inderal, Pravachol, Prothiaden.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 189792 **Seq:** 1
Reported: 25/08/2003
Hospitalisation:
Onset Date: 14/08/2003
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 62
DOB: 05/11/1940
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Severe arthralgia affecting wrists, hands, knees, ankles.	

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/08/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/08/2003	Other data				

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 189862 **Seq:** 1 **Gender:** M
Reported: 26/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Myalgia	

Medicine Details:

AVANZA (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 189902 **Seq:** 1 **Gender:** F
Reported: 28/08/2003 **Weight:** 50.00
Hospitalisation: **Age:** 81
Onset Date: 20/08/2003 **DOB:** 25/12/1921
Outcome: Recovered 21/08/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, visual		Visual hallucinations that night.	Nil.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 20/08/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other medications taken: Cardizem, Flixotide, Imdur, Karvezide, Lipitor, Losec.
Too Mirtazapine again next night and was OK.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 189985 **Seq:** 1 **Gender:** M
Reported: 31/08/2003 **Weight:** 76.00
Hospitalisation: **Age:** 56Y
Onset Date: 15/07/2003 **DOB:**
Outcome: Recovered without treatment **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Severe	weight gain, increased appetite, extreme irritability, swollen joints, restless legs, problems with enunciation, driving capabilty reduced	stopped medication
Disturbance in attention	Severe		
Dysarthria	Severe		
Increased appetite	Severe		
Irritability	Severe		
Joint swelling	Severe		
Restless legs syndrome	Severe		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Capsule 15.0 Milligram Daily Oral
Batch: **Started:** 06/06/2003 **Stopped:** 28/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 190320 **Seq:** 1 **Gender:** M
Reported: 08/09/2003 **Weight:** 80.00
Hospitalisation: **Age:** 19
Onset Date: **DOB:** 24/09/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia	Required Visit to Doctor	Rapid hair loss	

Medicine Details:

EPILIM (Suspected) **Reason:** Epilepsy
Tablet 1.0 Gram Daily Oral
Batch: **Started:** 10/06/2003 **Stopped:** 08/07/2003

AVANZA (Suspected) **Reason:** Depression
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 16/06/2003 **Stopped:** 08/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 190298 is seq 1.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 190388 **Seq:** 1 **Gender:** M
Reported: 10/09/2003 **Weight:** 80.00
Hospitalisation: **Age:** 49
Onset Date: 12/08/2003 **DOB:** 27/07/1954
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Short lived flashes in visual field "like a mirror reflecting sunlight".	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 11/08/2003 **Stopped:** 12/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 190521 **Seq:** 1 **Gender:** F
Reported: 15/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 15/07/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Convulsions	

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 10/07/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of childhood seizures, but had not had a seizure for some years.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 190734 **Seq:** 1 **Gender:** F
Reported: 22/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 88
Onset Date: 07/05/2003 **DOB:** 08/12/1914
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	Patient found collapsed, confused and hypothermic outside her home in the early hours of the morning. Subsequently found to have colles fracture of wrist. Two days before had been started on Mirtazapine. Had been taking tramadol at night for some time.	Cease mirtazepine and tramadol. IV fluids.
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Suspected) **Reason:**

Tablet	15.0 Milligram	1 time		Oral
Batch:	**Started:** 05/05/2003		**Stopped:**	07/05/2003

TRAMADOL HYDROCHLORIDE (Suspected) **Reason:**

Tablet, modified release	100.0 Milligram	Daily		Oral
Batch:	**Started:**		**Stopped:**	07/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 190896 is a duplicate of this report.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 190734 **Seq:** 1 **Gender:** F
Reported: 22/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 88
Onset Date: 07/05/2003 **DOB:** 08/12/1914
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disorientation	Caused or prolonged inpatient hospitalisation		
Hypothermia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 15.0 Milligram 1 time Oral
Batch: **Started:** 05/05/2003 **Stopped:** 07/05/2003

TRAMADOL HYDROCHLORIDE (Suspected) **Reason:**
Tablet, modified release 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 07/05/2003

Laboratory Investigations:

Additional Information:

Report 190896 is a duplicate of this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 190893 **Seq:** 1
Reported: 25/09/2003
Hospitalisation: Admitted to hospital
Onset Date: 07/08/2003
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 62
DOB: 14/11/1940
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Life [illegible]	Pneumonia, delirium, acalculous cholecystitis, pulmonary embolus	
Cholecystitis	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 30/07/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: galantamine,Vioxx, Lipitor, Vitamin E and Vitamin C, Ginkgo Biloba, Folic Acid.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 190893 **Seq:** 1
Reported: 25/09/2003
Hospitalisation: Admitted to hospital
Onset Date: 07/08/2003
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 62
DOB: 14/11/1940
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ileus paralytic	Caused or prolonged inpatient hospitalisation		
Pulmonary embolism	Caused or prolonged inpatient hospitalisation		
Respiratory distress	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 30/07/2003 **Stopped:**

Laboratory Investigations:

Additional Information:

Patient also administered: galantamine,Vioxx, Lipitor, Vitamin E and Vitamin C, Ginkgo Biloba, Folic Acid.

Report Detail

Case Number: 190934 **Seq:** 1 **Gender:** F
Reported: 14/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 07/07/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Metrorrhagia	Required Visit to Doctor	Breakthrough bleeding, menstrual	
Menstruation irregular	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Avanza was started sometime in Feb 2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 190966 **Seq:** 1 **Gender:** F
Reported: 29/09/2003 **Weight:** 86.00
Hospitalisation: **Age:** 71
Onset Date: 23/08/2003 **DOB:** 11/08/1932
Outcome: Recovered 15/09/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthritis	Required Visit to Doctor	Severe arthritic pain in the knees and	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 21/08/2003 **Stopped:** 02/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Vioxx, Zocor, Temaze, Zanidip and Atacand.

Report Detail

Case Number: 191037 **Seq:** 1
Reported: 02/10/2003
Hospitalisation:
Onset Date: 16/09/2003
Outcome: Not yet recovered

Gender: M
Weight: 65.00
Age: 33
DOB: 29/08/1970
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare	Required Visit to Doctor	Nightmares	Discussion

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 15/09/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191076 **Seq:** 1
Reported: 03/10/2003
Hospitalisation:
Onset Date: 01/02/2003
Outcome: Not yet recovered

Gender: M
Weight: 58.00
Age: 45
DOB: 27/09/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual acuity reduced	Required Visit to Doctor	Loss of viusal acuity.	2 new sets of glasses in the last 6 months.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 2.0 Dose Unspecified Daily Oral

Batch: **Started:** 24/01/2002 **Stopped:** Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of etoH abuse, illicit substance use, no history of diabetes claims onset of reaction coincides with starting Avanza.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191339 **Seq:** 1 **Gender:** M
Reported: 15/10/2003 **Weight:** 64.00
Hospitalisation: **Age:** 62
Onset Date: **DOB:** 04/07/1941
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pollakiuria	Required Visit to Doctor	Increased urinary frequency.	

Medicine Details:

AVANZA (Suspected) **Reason:**

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Calcium, Celebrex, Loperamide, Noten, Pressin.
In absence of demonstrable prostate disease.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191371 **Seq:** 1
Reported: 16/10/2003
Hospitalisation:
Onset Date: 25/09/2003
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 27
DOB: 06/06/1976
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Required Visit to Doctor	Facial rash - clinically similar to schorrheic dermatitis.	Stopped Mirtazapine.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 24/09/2003 **Stopped:** 28/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191387 **Seq:** 1 **Gender:** M
Reported: 17/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 20/08/2002 **DOB:** 24/01/1967
Outcome: Recovered 03/09/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Violent ideation	Required Visit to Doctor	Patient had a PH of OCD and presented with depression and violent thoughts. s.	Mirtazepine ceased, Efexan

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 11/06/2002 **Stopped:** 20/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had PH of OCI when not depressed, acted on the violent thoughts.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191393 **Seq:** 1 **Gender:** F
Reported: 17/10/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered 03/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancytopenia	Caused or prolonged inpatient hospitalisation	Severe pancytopenia on addition of Avanza to her usual medications.	

Medicine Details:

REMERON (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 31/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Didrocal, Evista, Methotrexate.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191403 **Seq:** 1
Reported: 17/10/2003
Hospitalisation: Admitted to hospital
Onset Date: 15/05/2002
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 47
DOB: 09/07/1954
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder	Caused or prolonged inpatient hospitalisation	DEPRESSION AND PANIC DISORDER, OCD CHARACTERIZED BY MARKED OBSESSIONAL CHECKING.	Mirtazepine ceased and numerous other anti-depressants and anti OCD treatments used. ECT.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** 15/01/2002 **Stopped:** 22/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No past history of OCD or obsessions.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191425 **Seq:** 1
Reported: 20/10/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 87.00
Age: 59
DOB: 14/10/1944
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood cholesterol increased		Depression, oedema of legs/ankle, cholesterol increased, LFT's abnormal, hypoglycaemia.	
Depression	Required Visit to Doctor	Depression, oedema of legs/ankle, cholesterol increased, LFT's abnormal, hypoglycaemia.	
Ascites			
Hypoglycaemia			
Liver function test abnormal			
Oedema peripheral			

Medicine Details:

AVANZA (Suspected) **Reason:**

1.0 Dose Unspecified Daily

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Tenormin, Felodur. Background history of alcoholism with prior abnormalities in LFTs. Feels Avanza has exacerbated the problem. Onset of reaction October 2003

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191454 **Seq:** 1 **Gender:** F
Reported: 21/10/2003 **Weight:** 70.00
Hospitalisation: **Age:** 76
Onset Date: 14/09/2003 **DOB:** 08/02/1927
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Lichenoid keratosis		Follicular based lichenoid eruption abdomen and back very itchy.	Treated with Elocon, ceased Mirtazapine.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/10/2003	Skin biopsy				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191461 **Seq:** 1 **Gender:** F
Reported: 21/10/2003 **Weight:** 65.00
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 21/01/1965
Outcome: Recovered 14/09/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle fatigue Myopathy	Required Visit to Doctor	Myopathy like fatigue gradually with in the muscles particularly 1-2 weeks of quadriceps/thighs, unable to lift legs.	Cessation of drug.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 10/07/2003 **Stopped:** 10/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191635 **Seq:** 1
Reported: 27/10/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 68.00
Age: 53
DOB: 26/05/1950
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia	Required Visit to Doctor	Myalgia, arthralgia	Ceased Lipitor, treated with Prednisolone.
Arthralgia	Severe		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/10/2003	Creatine				

Additional Information:

Severe symptoms during wothdrawal of Avanza. Did not have symptoms while on Avanza except at low dose prior to ceasing. had been on Lipitor for > 1 year prior to problem. No improut on ceasing Lipitor.
ESR 27 serogical tests for inflammary arthritis negative but rapid complete response to prednisolone 25mg. Reduced successfully to 5mg.
Patient was also taking Lipitor, Isoptin SR, temazepam, Estraderm.
Reaction was sometime in october 2002.

Report Detail

Case Number: 191653 **Seq:** 1 **Gender:** F
Reported: 27/10/2003 **Weight:** 58.00
Hospitalisation: **Age:** 47
Onset Date: 14/10/2003 **DOB:** 04/09/1956
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia		Akathisia	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Have had a number of women suffer brief or prolonged akathisia.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191677 **Seq:** 1 **Gender:** M
Reported: 28/10/2003 **Weight:** 72.00
Hospitalisation: **Age:** 50
Onset Date: 01/12/2002 **DOB:** 06/07/1952
Outcome: Recovered 03/12/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sedation		Sedation for 48 hours after 1st dose of	

Medicine Details:

LIPITOR (Other drug) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
30.0 Milligram 1 time
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191725 **Seq:** 1 **Gender:** F
Reported: 29/10/2003 **Weight:** 60.00
Hospitalisation: **Age:** 31
Onset Date: 06/10/2003 **DOB:** 27/01/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Probable seizure, found on side of road confused and with back pain.	
Back pain	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RAFEN (Other drug) **Reason:** Pain
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 01/08/2003 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/08/2003 **Stopped:** 07/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug: Methadone for opiate dependence.
Took 3 x vodkas on the same night as reaction.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191756 **Seq:** 1 **Gender:** F
Reported: 30/10/2003 **Weight:** 72.00
Hospitalisation: **Age:** 65
Onset Date: 21/10/2003 **DOB:** 21/05/1938
Outcome: Recovered 24/10/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bone marrow failure	Required Visit to Doctor	Bone marrow depression.	

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 15/04/2003 **Stopped:** 21/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/10/2003	Platelets		21/10/2003	53	
30/10/2003	White blood cells		21/10/2003	3.9	

Additional Information:

Repeated tests (platelets, WCC) on 24/10/03 - NAD.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 191841 **Seq:** 1
Reported: 04/11/2003
Hospitalisation:
Onset Date: 30/09/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 33
DOB: 05/12/1969
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Depression Increased appetite Sedation		Excessive weight gain, increased appetite, depression and excessive sedation.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 30/09/2003 **Stopped:** 13/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Co morbid anxiety disorder, possibly worse.

Report Detail

Case Number: 192104 **Seq:** 1
Reported: 11/11/2003
Hospitalisation:
Onset Date: 08/11/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 38
DOB: 24/01/1965
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation	Elation, excitement, euphoria, irritability, restlessness and racing thoughts.	Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness.
Euphoric mood	Caused or prolonged inpatient hospitalisation	Elation, excitement, euphoria, irritability, restlessness and racing thoughts.	Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness.
Inappropriate affect	Caused or prolonged inpatient hospitalisation	Elation, excitement, euphoria, irritability, restlessness and racing thoughts.	Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness.

Medicine Details:

EFEXOR (Interaction) **Reason:**
Tablet 37.5 Milligram 1 time Oral
Batch: **Started:** 07/11/2003 **Stopped:** 09/11/2003

Mirtazon (Interaction) **Reason:**
Tablet 60.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Other drug) **Reason:**
Tablet 5.0 Milligram 2 times Oral
Batch: **Started:** **Stopped:**

ANTENEX (Other drug) **Reason:**
Tablet 5.0 Milligram As necessary Oral
Batch: **Started:** 02/11/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 192104 **Seq:** 1
Reported: 11/11/2003
Hospitalisation:
Onset Date: 08/11/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 38
DOB: 24/01/1965
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Irritability	Caused or prolonged inpatient hospitalisation	Elation, excitement, euphoria, irritability, restlessness and racing thoughts.	Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness.
Restlessness	Caused or prolonged inpatient hospitalisation	Elation, excitement, euphoria, irritability, restlessness and racing thoughts.	Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness.
Thinking abnormal	Caused or prolonged inpatient hospitalisation	Elation, excitement, euphoria, irritability, restlessness and racing thoughts.	Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness.

Medicine Details:

PANADOL (Other drug) **Reason:**
Tablet 500.0 Milligram As necessary Oral
Batch: **Started:** 02/11/2003 **Stopped:** 08/11/2003

LARGACTIL (Other drug) **Reason:**
Tablet 50.0 Milligram As necessary Oral
Batch: **Started:** 02/11/2003 **Stopped:**

ZYPREXA (Other drug) **Reason:**
Tablet 50.0 Milligram As necessary Oral
Batch: **Started:** 02/11/2003 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 192164 **Seq:** 1 **Gender:** F
Reported: 13/11/2003 **Weight:** 80.00
Hospitalisation: **Age:** 62
Onset Date: 05/11/2003 **DOB:** 10/07/1941
Outcome: Recovered 06/11/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Clumsiness		Dropping things	
Somnolence		Groggy, dry mouth.	
Feeling abnormal		Not with it.	
Dry mouth			

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 04/11/2003 **Stopped:** 05/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Premarin and Celebrex.
Reacted badly to 1/2 Serepax years ago.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 192309 **Seq:** 1 **Gender:** F
Reported: 18/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 45
Onset Date: 07/09/2003 **DOB:** 25/09/1957
Outcome: Recovered 21/09/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus	Required Visit to Doctor	Patient developed itchy, red rash with 'raised lumps' - like acne but no head!	OTC Histamine
Rash erythematous	Required Visit to Doctor		
Urticaria	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 16/08/2003 **Stopped:** 07/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Started 3/52 after starting Avanza. Stopped Avanza and rash settled after 2/52.
Patient also administered: Methadone Liquid, Amphetamine IV.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 192383 **Seq:** 1 **Gender:** F
Reported: 21/11/2003 **Weight:** 80.00
Hospitalisation: **Age:** 48
Onset Date: 15/08/2003 **DOB:** 31/10/1954
Outcome: Recovered 19/11/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	Oedematous lower legs.	Avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 23/01/2003 **Stopped:** 12/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction developed 6 months after starting Avanza and resolved within a week of stopping Avanza.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 192726 **Seq:** 1 **Gender:** F
Reported: 02/12/2003 **Weight:** 100.00
Hospitalisation: **Age:** 51
Onset Date: 24/10/2003 **DOB:** 25/04/1952
Outcome: Recovered 24/10/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Febrile	
Feeling cold	Caused or prolonged inpatient hospitalisation	Feeling cold, tremors, difficulty breathing and febrile.	Dithiazide ceased. Given oral potassium supplement.
Hypokalaemia	Caused or prolonged inpatient hospitalisation	Feeling cold, tremors, difficulty breathing and febrile.	Dithiazide ceased. Given oral potassium supplement.

Medicine Details:

Dithiazide Hydrochlorothiazide (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 24/10/2003 **Stopped:**

SOMAC (Suspected) **Reason:** Other diseases of esophagus
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2003	Calcium		24/10/2003	2.03	
02/12/2003	Potassium		24/10/2003	3.3	

Additional Information:

Reactions occurred 1 hour after dose of dithiazide.
Patient has tolerated thiazides previously but not in the presence of Somac and Avanza. Patient also taking Thyroxine, Rocaltrol, Caltrate, Panadeine Forte and Noten.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 192726 **Seq:** 1 **Gender:** F
Reported: 02/12/2003 **Weight:** 100.00
Hospitalisation: **Age:** 51
Onset Date: 24/10/2003 **DOB:** 25/04/1952
Outcome: Recovered 24/10/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Dithiazide Hydrochlorothiazide (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 24/10/2003 **Stopped:**

SOMAC (Suspected) **Reason:** Other diseases of esophagus
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Reactions occurred 1 hour after dose of dithiazide.
Patient has tolerated thiazides previously but not in the presence of Somac and Avanza. Patient also taking Thyroxine, Rocaltrol, Caltrate, Panadeine Forte and Noten.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 192783 **Seq:** 1
Reported: 02/12/2003
Hospitalisation:
Onset Date: 20/11/2003
Outcome: Not yet recovered

Gender: M
Weight: 55.00
Age: 20
DOB: 21/12/1982
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Euphoric mood Asthenia Disorientation Dysphoria Visual disturbance		Euphoria, weakness, dysphoria, visual disturbances and disorientation.	Di-gesic ceased

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 2.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/11/2003 **Stopped:**

DI-GESIC (Suspected) **Reason:** Pain
8.0 Dose Unspecified Daily
Batch: **Started:** 19/11/2003 **Stopped:** 21/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 192890 **Seq:** 1 **Gender:** U
Reported: 05/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal			

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 192909 **Seq:** 1 **Gender:** U
Reported: 05/12/2003 **Weight:** 84.00
Hospitalisation: **Age:** 62Y
Onset Date: 15/11/2003 **DOB:**
Outcome: Recovered 22/11/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Agitation Restlessness		Tremor, agitation, restlessness when increased dose from half tablet to full tablet daily.	Ceased avanza

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 07/11/2003 **Stopped:** 20/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Coversyl Plus, Plendil SR, Methotrexate and prednisolone.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193154 **Seq:** 1 **Gender:** U
Reported: 15/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haemolytic anaemia	Caused or prolonged inpatient hospitalisation	Convulsion and haemolytic anaemia.	Transferred to ICU.

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Atorvastatin, Allopuinol, Warfarin, Phenytoin, Verapamil, Amiodarone.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193155 **Seq:** 1
Reported: 15/12/2003
Hospitalisation:
Onset Date: 27/06/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 76
DOB: 23/08/1926
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatremia and SIADH.	
Inappropriate antidiuretic hormon	Caused or prolonged inpatient hospitalisation		

Medicine Details:

REMERON (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 15/05/2002 **Stopped:** 09/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/12/2003	Other data				
15/12/2003	Sodium		27/06/2003	121	
15/12/2003	Urine osmolality		07/07/2003	484 mmol/kg	

Additional Information:

Suspect drug positive rechallenge.
The patient had also developed hyponatremia earlier in the treatment (in 2002). On that occasion Remeron dose was decreased and the patient had recovered.
Patient also administered: Acetylsalicylic acid, Thyroxine sodium, FGF Tabs, Perindopril, Selenium.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193225 **Seq:** 1 **Gender:** M
Reported: 16/12/2003 **Weight:** 100.00
Hospitalisation: **Age:** 50
Onset Date: 06/12/2003 **DOB:** 12/05/1953
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Migraine	Required Visit to Doctor	Nightmares, vivid dreams and sleep disturbances for the past week.	Refer to Doctor since migraine has not subsided and new treatment regime required.
Abnormal dreams	Required Visit to Doctor		
Nightmare	Required Visit to Doctor		
Sleep disorder	Required Visit to Doctor		

Medicine Details:

QUININE BISULPHATE (Suspected) **Reason:** Pain in limb
Tablet 300.0 Milligram As necessary Oral
Batch: **Started:** 20/11/2003 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

SANDOMIGRAN (Suspected) **Reason:** Migraine
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 20/11/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has taken suspect medications consistantly for the past three weeks. Patient also taking Tramal SR, Imigran, Ventolin, Serevent and Pulmicort.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193345 **Seq:** 1 **Gender:** F
Reported: 19/12/2003 **Weight:** 51.00
Hospitalisation: **Age:** 30
Onset Date: 29/11/2003 **DOB:** 31/08/1973
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hearing impaired	Required Visit to Doctor	Altered pitch of music, phone ringing, sounds are 'flat'.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 28/11/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 193457 **Seq:** 1
Reported: 22/12/2003
Hospitalisation:
Onset Date: 21/11/2003
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 66
DOB: 15/09/1937
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal	Required Visit to Doctor	Markedly elevated LFT's in background of liver disease.	

Medicine Details:

NEXIUM (Other drug) **Reason:** Other diseases of esophagus
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 15/07/2003 **Stopped:** 12/08/2003

ZOTON (Suspected) **Reason:** Other diseases of esophagus
60.0 Milligram Daily Oral
Batch: **Started:** 13/08/2003 **Stopped:** 01/12/2003

AVANZA (Suspected) **Reason:** Depression
Tablet 1.5 Dose Unspecified Daily Oral
Batch: **Started:** 21/09/2003 **Stopped:** 21/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/12/2003	ALT = SGPT		23/07/2003	28	
22/12/2003	ALT = SGPT		21/11/2003	172	
22/12/2003	ALT = SGPT		01/12/2003	237	
22/12/2003	AST = SGOT		23/07/2003	34	
22/12/2003	AST = SGOT		21/11/2003	268	
22/12/2003	AST = SGOT		01/12/2003	438	
22/12/2003	Bilirubin		23/07/2003	6	

Additional Information:

Patient also administered: Slow K, Lasix, Valium, Stilnox, Premarin, Neocytamen, Vit K, Flixotide, Serevent.

Report Detail

Case Number: 193457 **Seq:** 1
Reported: 22/12/2003
Hospitalisation:
Onset Date: 21/11/2003
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 66
DOB: 15/09/1937
Causality: Causality possible

Reaction Detail

Medicine Details:

NEXIUM (Other drug)			**Reason:**	Other diseases of esophagus	
Tablet	40.0	Milligram	Daily		Oral
Batch:	**Started:**	15/07/2003		**Stopped:**	12/08/2003
ZOTON (Suspected)			**Reason:**	Other diseases of esophagus	
	60.0	Milligram	Daily		Oral
Batch:	**Started:**	13/08/2003		**Stopped:**	01/12/2003
AVANZA (Suspected)			**Reason:**	Depression	
Tablet	1.5	Dose Unspecified	Daily		Oral
Batch:	**Started:**	21/09/2003		**Stopped:**	21/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/12/2003	Bilirubin		21/11/2003	14	
22/12/2003	Bilirubin		01/12/2003	14	
22/12/2003	GGT = SGGT =		23/07/2003	205	
22/12/2003	GGT = SGGT =		21/11/2003	1417	
22/12/2003	GGT = SGGT =		01/12/2003	1490	
22/12/2003	LDH		23/07/2003	151	
22/12/2003	LDH		21/11/2003	550	

Additional Information:

Patient also administered: Slow K, Lasix, Valium, Stilnox, Premarin, Neocytamen, Vit K, Flixotide, Serevent.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193457 **Seq:** 1
Reported: 22/12/2003
Hospitalisation:
Onset Date: 21/11/2003
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 66
DOB: 15/09/1937
Causality: Causality possible

Reaction Detail

Medicine Details:

NEXIUM (Other drug)			**Reason:**	Other diseases of esophagus	
Tablet	40.0	Milligram	Daily		Oral
Batch:	**Started:**	15/07/2003		**Stopped:**	12/08/2003
ZOTON (Suspected)			**Reason:**	Other diseases of esophagus	
	60.0	Milligram	Daily		Oral
Batch:	**Started:**	13/08/2003		**Stopped:**	01/12/2003
AVANZA (Suspected)			**Reason:**	Depression	
Tablet	1.5	Dose Unspecified	Daily		Oral
Batch:	**Started:**	21/09/2003		**Stopped:**	21/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/12/2003	LDH		01/12/2003	643	
22/12/2003	SAP = ALP		23/07/2003	108	
22/12/2003	SAP = ALP		21/11/2003	215	
22/12/2003	SAP = ALP		01/12/2003	262	

Additional Information:

Patient also administered: Slow K, Lasix, Valium, Stilnox, Premarin, Neocytamen, Vit K, Flixotide, Serevent.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193461 **Seq:** 1 **Gender:** F
Reported: 22/12/2003 **Weight:** 86.00
Hospitalisation: **Age:** 51
Onset Date: 11/12/2003 **DOB:** 11/04/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations	Required Visit to Doctor	Fluttering irregular heart beat.	
Arrhythmia	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 05/12/2003 **Stopped:** 16/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193580 **Seq:** 1 **Gender:** F
Reported: 06/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 76
Onset Date: 23/10/2003 **DOB:** 10/02/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain	Caused or prolonged inpatient hospitalisation	Body pain	
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation	Withdrawal reaction, chest pain with exacerbated dyskinesia.	Ceased Avanza
Chest pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Sinemet, Cabaser, Lipitor, Motilium, Coversyl, Somac.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193580 **Seq:** 1 **Gender:** F
Reported: 06/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 76
Onset Date: 23/10/2003 **DOB:** 10/02/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Patient was also taking Sinemet, Cabaser, Lipitor, Motilium, Coversyl, Somac.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193747 **Seq:** 1
Reported: 09/01/2004
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 78.00
Age: 59
DOB: 24/06/1944
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis psoriasiform	Caused or prolonged inpatient hospitalisation	Psoriaform drug reaction.	Topical - wet dressing with

Medicine Details:

AVANZA (Suspected) **Reason:** Unspecifid affective psychosis

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2004	Skin biopsy				

Additional Information:

Onset date: late Oct 2003. Dose start and stop date: 10/03 and 12/03.

Report Detail

Case Number: 193807 **Seq:** 1 **Gender:** M
Reported: 12/01/2004 **Weight:** 111.00
Hospitalisation: **Age:** 51
Onset Date: 20/12/2003 **DOB:** 25/01/1952
Outcome: Recovered without treatment 03/01/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia	Required Visit to Doctor	After first dose, gradual onset of patchy glove and stocking loss of sensation and proximal muscle weakness (2-3/5 power) with elevated CK. Fell twice due to collapse of legs.	Nil.
Blood creatine phosphokinase in	Required Visit to Doctor		
Fall	Required Visit to Doctor		
Lethargy	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 19/12/2003 **Stopped:** 23/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/01/2004	Creatine		20/12/2003	223	

Additional Information:

Exposure re-challenged x 1 dose of 15mg on 6/1/2004 with beginnings of same effect.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193807 **Seq:** 1 **Gender:** M
Reported: 12/01/2004 **Weight:** 111.00
Hospitalisation: **Age:** 51
Onset Date: 20/12/2003 **DOB:** 25/01/1952
Outcome: Recovered without treatment 03/01/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscular weakness	Required Visit to Doctor		
Myalgia	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 19/12/2003 **Stopped:** 23/12/2003

Laboratory Investigations:

Additional Information:

Exposure re-challenged x 1 dose of 15mg on 6/1/2004 with beginnings of same effect.

Report Detail

Case Number: 193836 **Seq:** 1 **Gender:** M
Reported: 12/01/2004 **Weight:** 79.00
Hospitalisation: **Age:** 45Y
Onset Date: 16/11/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Severe mood swings and agitated.	
Mood swings	Required Visit to Doctor	Severe mood swings and agitated.	

Medicine Details:

AROPAX (Other drug) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 10/11/2003

LITHIUM CARBONATE (Other drug) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** Contin

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 11/11/2003 **Stopped:** 16/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Abrupt censation of Aropax and commenced Avanza.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193906 **Seq:** 1 **Gender:** F
Reported: 15/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 70
Onset Date: 09/01/2004 **DOB:** 22/01/1933
Outcome: Recovered 09/01/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Epileptiform seizure when started on Avanza occurred with 2nd dose.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 08/01/2004 **Stopped:** 09/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Fosamax and Inderal.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 193959 **Seq:** 1
Reported: 19/01/2004
Hospitalisation:
Onset Date: 08/07/2003
Outcome: Not yet recovered

Gender: M
Weight: 78.00
Age: 48
DOB: 13/03/1955
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood cholesterol increased	Required Visit to Doctor	Cholesterol total increased, HDL/cholesterol increased, Triglycerides increased.	
Blood triglycerides increased	Required Visit to Doctor		
Total cholesterol/HDL ratio decre	Required Visit to Doctor		

Medicine Details:

EFEXOR (Suspected) **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/01/2004	Cholesterol				
19/01/2004	High density				
19/01/2004	Triglyceride				

Additional Information:

Report Detail

Case Number: 194019 **Seq:** 1 **Gender:** M
Reported: 21/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 69
Onset Date: 28/12/2003 **DOB:** 09/12/1934
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Caused or prolonged inpatient hospitalisation	Hepatic enzyme increased, abdominal	
Hepatic enzyme increased	Caused or prolonged inpatient hospitalisation	Hepatic enzyme increased, abdominal	Gall bladder removed
Biliary colic	Caused or prolonged inpatient hospitalisation		

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 11/11/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/01/2004	Liver biopsy				

Additional Information:

Other drugs: Acetylsalicylic Acid, Atorvastatin, Clopidogrel and Ramipril. History: No previous history of liver problems and cardiac problems.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194186 **Seq:** 1 **Gender:** F
Reported: 30/01/2004 **Weight:** 59.00
Hospitalisation: **Age:** 14Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eczema		Worsening of eczema over eyelids.	Hydrocortisone cream.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 10/12/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous history of ezcema allergy.

Report Detail

Case Number: 194225 **Seq:** 1 **Gender:** F
Reported: 03/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 70Y
Onset Date: 28/10/2003 **DOB:**
Outcome: Recovered 06/11/2003 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast tenderness	Required Visit to Doctor	Breast tenderness.	

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 28/10/2003 **Stopped:** 04/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tried again a 2nd time. 2nd episode of breast tenderness, confirming that it was due to the Avanza.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194236 **Seq:** 1 **Gender:** F
Reported: 03/02/2004 **Weight:** 90.00
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 20/08/1973
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Intentional self-injury		Suicidal ideation, deliberate self harm.	

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Other drug) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Self harm thoughts remitted on withdrawal of drug.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194417 **Seq:** 1
Reported: 09/02/2004
Hospitalisation:
Onset Date: 01/02/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Required Visit to Doctor	Rash, mouth ulcers, flushing skin (hot and blotchy), restless legs, hungry.	
Flushing	Required Visit to Doctor	Skin hot and blotchy.	
Hunger	Required Visit to Doctor		
Mouth ulceration	Required Visit to Doctor		
Restless legs syndrome	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 27/01/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Asig, Astrix, Diazepam and Norvasc.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194487 **Seq:** 1 **Gender:** M
Reported: 10/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: 19/01/2004 **DOB:** 28/12/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Alanine aminotransferase increas Aspartate aminotransferase incre Oedema		Weight increased, oedema, ALT increased, AST increased.	

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet Dose Unspecified
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/02/2004	ALT = SGPT				74
10/02/2004	AST = SGOT				57
10/02/2004	Other data				All others normal.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194574 **Seq:** 1 **Gender:** F
Reported: 13/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: 05/02/2004 **DOB:** 19/10/1954
Outcome: Recovered 09/02/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular	Required Visit to Doctor	Patient developed a maculopapular rash over trunk, various mouth ulcers over bottom of mouth and tongue and also suspected nose bleeds and bruising.	
Contusion	Required Visit to Doctor		
Epistaxis	Required Visit to Doctor		
Mouth ulceration	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 03/02/2004 **Stopped:** 05/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Pariet, Sandragel, Hydromorphone, Methadone and Paracetamol.

Report Detail

Case Number: 194662 **Seq:** 1 **Gender:** F
Reported: 16/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 76Y
Onset Date: 27/01/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hot flush Drug withdrawal syndrome Panic attack		Feeling of hot flushes - waves of heat over whole body, panic attack, withdrawal reaction.	Xanax was not effective.

Medicine Details:

TENORMIN (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** Contin

AVANZA (Suspected) **Reason:**
Tablet 30.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 25/01/2004

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily
Batch: **Started:** 26/01/2004 **Stopped:** 28/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194681 **Seq:** 1 **Gender:** F
Reported: 16/02/2004 **Weight:** 62.00
Hospitalisation: **Age:** 66Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Required Visit to Doctor	Seizures, agitation, flushing, confusion, sensory disturbances of feet, ataxia.	
Agitation	Required Visit to Doctor		
Confusional state	Required Visit to Doctor		
Coordination abnormal	Required Visit to Doctor		
Flushing	Required Visit to Doctor		
Sensory disturbance	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 60.0 Milligram Daily
Batch: **Started:** **Stopped:**

TRAMAL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily
Batch: **Started:** **Stopped:**

SINEQUAN (Suspected) **Reason:**
75.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194692 **Seq:** 1 **Gender:** M
Reported: 17/02/2004 **Weight:** 84.66
Hospitalisation: **Age:** 48
Onset Date: 11/02/2004 **DOB:** 02/07/1955
Outcome: Recovered 13/02/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensory disturbance Snoring		Got up and felt like he was in a boat, affecting balance.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 11/02/2004 **Stopped:** 13/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Depression.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194758 **Seq:** 1 **Gender:** F
Reported: 19/02/2004 **Weight:** 98.00
Hospitalisation: **Age:** 47
Onset Date: 13/02/2004 **DOB:** 22/09/1956
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal distension	Required Visit to Doctor	Bloating, fluid retention - upper and lower limbs, lethargy, palpitations, headaches, tachycardia, Increased SOB.	
Dyspnoea	Required Visit to Doctor		
Fluid retention	Required Visit to Doctor		
Headache	Required Visit to Doctor		
Lethargy	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 07/02/2004 **Stopped:** 13/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194758 **Seq:** 1 **Gender:** F
Reported: 19/02/2004 **Weight:** 98.00
Hospitalisation: **Age:** 47
Onset Date: 13/02/2004 **DOB:** 22/09/1956
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations	Required Visit to Doctor		
Tachycardia	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 07/02/2004 **Stopped:** 13/02/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194789 **Seq:** 1 **Gender:** U
Reported: 20/02/2004 **Weight:** 70.00
Hospitalisation: **Age:** 78
Onset Date: **DOB:** 30/11/1925
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Abnormal liver function tests - ALP, GGT, ALT, AST progressively increasing.	Change from Mirtazepine, LFT's normal.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 45.0 Milligram Daily
Batch: **Started:** 01/03/2003 **Stopped:** 30/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Atacand plus, Noten, Pravachol.
Recently to normal after replaced by Efexor-XR.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 194831 **Seq:** 1 **Gender:** F
Reported: 23/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 61
Onset Date: **DOB:** 21/03/1942
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome	Required Visit to Doctor	Restless leg syndrome	Recovered 2/7 after cessation.

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Dose Unspecified
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Methotrexate, Prednisolone, Stilnox, Epilim, Serc.
Avanza late 2003 - developed restless legs - ceased - 2/7 later, resolved.

Report Detail

Case Number: 195081 **Seq:** 1 **Gender:** F
Reported: 03/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 85
Onset Date: 02/08/2003 **DOB:** 14/07/1918
Outcome: Recovered 05/08/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paranoia Aggression Confusional state Drug withdrawal syndrome		Paranoia, violent behavior, confusional state, withdrawal reaction.	

Medicine Details:

REMERON (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 26/07/2003 **Stopped:** 01/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Esomeprazole and Paracetamol.
Threatened the staff at residence with a knife. Police were involved in disarming her.

Report Detail

Case Number: 195216 **Seq:** 1 **Gender:** F
Reported: 09/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 46Y
Onset Date: 19/02/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombosis	Caused or prolonged inpatient hospitalisation	Thrombosis (in both legs), edema legs	Heparin and Warfarin.
Oedema peripheral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 15.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/03/2004	Other data				

Additional Information:

Patient also administered: Venlafaxine, Temazepam, Trisequens.
Reporting doctor said that the patient did not have any risk factors.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 195462 **Seq:** 1 **Gender:** M
Reported: 12/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 40
Onset Date: 25/12/2003 **DOB:** 16/08/1963
Outcome: Recovered with sequelae 25/12/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	4 grand mal seizures.	I/P Phenytoin

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Interaction) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** 29/11/2003 **Stopped:**

MIRTAZAPINE (Interaction) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 18/12/2003 **Stopped:** 25/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Zithromax and Clonazepam. No previous history.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 195471 **Seq:** 1 **Gender:** F
Reported: 12/03/2004 **Weight:** 76.00
Hospitalisation: **Age:** 31Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Incidental finding of increased hepatic enzymes, no jaundice	
Fatigue Influenza like illness		Tiredness, flu-like malaise.	Mirtazapine ceased

Medicine Details:

IMIPRAMINE HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** L TERM **Stopped:**

PARACETAMOL (Other drug) **Reason:** As necessary
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 12/12/2003 **Stopped:** 10/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/03/2004	ALT = SGPT	<31	04/03/2004	95	
12/03/2004	Biochemistry				
12/03/2004	GGT = SGGT =	5-36	04/03/2004	147	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 195520 **Seq:** 1 **Gender:** F
Reported: 16/03/2004 **Weight:** 61.00
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 09/11/1953
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Ankles puffy after one month.	
Urinary tract infection		Kept presenting with symptoms of UTI-inflamed urethra, frequency, and incontinence but twice no organisms cultured	
Oedema peripheral		Over a period of 3 months oedema up to knees, (pitting)	
Pain in extremity		Pain in legs immediately	Avanza ceased
Pollakiuria			
Urinary incontinence			

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Diaformin, Diamicron, Oroxine, doxycycline, lisinopril, Lipex, Brufen and paracetamol. All symptoms resolved almost immediately after Avanza ceased.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 195532 **Seq:** 1 **Gender:** M
Reported: 16/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 75Y
Onset Date: 04/02/2004 **DOB:**
Outcome: Recovered 06/02/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypersomnia	Severe	Slept for 15 hours, woke up a zombie, had headache, symptoms persisted for 12 hours after waking up.	Drug ceased by patient.
Feeling abnormal	Severe		
Headache	Severe		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 04/02/2004 **Stopped:** 05/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Nexium, Glucosamine and Viagra.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 195748 **Seq:** 1 **Gender:** M
Reported: 19/03/2004 **Weight:** 70.00
Hospitalisation: **Age:** 83
Onset Date: **DOB:** 30/10/1920
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams	Required Visit to Doctor	Bad dreams, recurring nightmares.	
Nightmare	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose start and stop date: 14/03 - 02/04

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 195871 **Seq:** 1 **Gender:** M
Reported: 23/03/2004 **Weight:** 85.00
Hospitalisation: **Age:** 60Y
Onset Date: 16/03/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sedation	Severe	Extreme "druggedness" (constant).	Ceased after advice from
Dysgeusia	Severe	Food bitter to taste.	
Hallucination	Severe	Hallucinations (during half awake state).	
Nightmare	Severe	Severe night-long nightmares.	Ceased after advice from
Sleep apnoea syndrome	Severe	Sleep apnoea (reported by wife lasting up to 15/20 seconds).	
Sleep disorder	Severe	Sleep disorder (violent thrashing around in bed, unable to wake self up).	

Medicine Details:

Mirtazon (Suspected) **Reason:**
Tablet Dose Unspecified Daily Oral
Batch: 594005/612492 **Started:** 15/03/2004 **Stopped:** 21/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 195917 **Seq:** 1
Reported: 24/03/2004
Hospitalisation:
Onset Date: 24/02/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 34
DOB: 12/12/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne	Required Visit to Doctor	Developed severe facial acne.	Skin cleanser.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 20/02/2004 **Stopped:** 02/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 195940 **Seq:** 1 **Gender:** M
Reported: 25/03/2004 **Weight:** 61.00
Hospitalisation: **Age:** 36
Onset Date: 12/02/2004 **DOB:** 19/02/1967
Outcome: Recovered 01/03/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fluid retention	Required Visit to Doctor	Severe fluid retention and swelling of both hands with painful oedema.	Ceased Mirtazapine
Oedema peripheral	Required Visit to Doctor		
Pain	Required Visit to Doctor		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 28/01/2004 **Stopped:** 09/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was aslo taking Methadone and Vioxx.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 196282 **Seq:** 1 **Gender:** M
Reported: 06/04/2004 **Weight:** 70.00
Hospitalisation: **Age:** 64
Onset Date: 21/03/2004 **DOB:** 10/04/1939
Outcome: Recovered 02/04/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gingivitis	Required Visit to Doctor	Gingivitis, mouth ulcers, neutropenia, increased CRP.	Mirtazapine ceased.
C-reactive protein increased	Required Visit to Doctor		
Mouth ulceration	Required Visit to Doctor		
Neutropenia	Required Visit to Doctor		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** 01/01/2004 **Stopped:** 23/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 196336 **Seq:** 1 **Gender:** F
Reported: 08/04/2004 **Weight:** 60.00
Hospitalisation: **Age:** 44
Onset Date: 28/03/2004 **DOB:** 25/06/1959
Outcome: Recovered 02/04/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Back pain		Patient experienced low back pain.	Ceased Avanza.

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 21/03/2004 **Stopped:** 31/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previously used 10/2003. Patient started on 1/4 a tablet than increased to 1/2 a tablet when reaction occurred.

Report Detail

Case Number: 196518 **Seq:** 1 **Gender:** F
Reported: 16/04/2004 **Weight:** 43.00
Hospitalisation: **Age:** 86
Onset Date: 26/03/2004 **DOB:** 28/06/1917
Outcome: Recovered with sequelae 06/04/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Inappropriate antidiuretic hormon		Patient experienced elevated transaminases and bilirubin within normal limits	Withdrawal of Mirtazapine 30mg. Admitted for investigation of SIADH

Medicine Details:

AUGMENTIN DUO FORTE (Suspected) **Reason:** Othr diseases of urinary tract
Tablet 2.0 Dose Unspecified Daily Oral
Batch: **Started:** 16/03/2004 **Stopped:** 19/03/2004

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 17/03/2004 **Stopped:** 25/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/04/2004	ALT = SGPT				ALT=60
16/04/2004	AST = SGOT				AST=47
16/04/2004	Bilirubin				BIL=normal.
16/04/2004	GGT = SGGT =				GGT=96
16/04/2004	LDH				LDH=350
16/04/2004	SAP = ALP				ALP=175

Additional Information:

Xalatan, Vitamin E, Karvea, Mogadon, Coloxyl and Senna.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 196546 **Seq:** 1 **Gender:** M
Reported: 19/04/2004 **Weight:** 85.00
Hospitalisation: **Age:** 59
Onset Date: 28/11/2003 **DOB:** 12/03/1944
Outcome: Recovered 14/01/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor	Patient experienced ongoing nausea, failed to improve, persistent during the day.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 21/11/2003 **Stopped:** 12/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 196572 **Seq:** 1
Reported: 19/04/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood pressure systolic decrease	Caused or prolonged inpatient hospitalisation	Blood pressure systolic decreased.	Treated in ER and kept for 24 hours observations.

Medicine Details:

REMERON (Suspected) **Reason:**

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2004	Blood pressure				

Additional Information:

Other drugs: Tramadol and Influenza Vaccine. Reaction occurred on the first dose.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 196819 **Seq:** 1 **Gender:** M
Reported: 27/04/2004 **Weight:** 83.00
Hospitalisation: **Age:** 58Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome	Required Visit to Doctor	Restless legs, muscle aches and pains, lack of motivation	Paracetamol, celebrex, tramadol. Avanza weaned off
Apathy	Required Visit to Doctor		
Myalgia	Required Visit to Doctor		

Medicine Details:

VALIUM (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

LIPEX (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Started avanza in September 2003 and stopped early April 2004

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 196909 **Seq:** 1
Reported: 29/04/2004
Hospitalisation:
Onset Date: 09/04/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 51
DOB: 28/08/1952
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Required Visit to Doctor	Weight gain (5kgs in 7 days, oedema, generalised muscle aches.	
Myalgia	Required Visit to Doctor		
Oedema	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 07/04/2004 **Stopped:** 16/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 196965 **Seq:** 1
Reported: 03/05/2004
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: U
Weight: 0.00
Age: 77
DOB: 02/06/1926
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Life	Hyponatraemia leading to cerebral oedema and fitting.	Intubation and given Mannitol.
Brain oedema	Life		
Convulsion	Life		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/12/2003 **Stopped:** 22/04/2004

AMISULPRIDE (Suspected) **Reason:**
300.0 Milligram Daily
Batch: **Started:** 01/03/2004 **Stopped:**

THIAMINE (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 01/03/2004 **Stopped:** Continuing

TEMAZEPAM (Suspected) **Reason:** Specific disorders of sleep
10.0 Milligram Daily Oral
Batch: **Started:** 01/12/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/05/2004	Sodium				

Additional Information:

Patient also taking Betoptic and Xalatan.
Had been on Mirtazapine since December 03, was increased February 04.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 197180 **Seq:** 1 **Gender:** M
Reported: 10/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 78Y
Onset Date: 31/01/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence	Caused or prolonged inpatient hospitalisation	Drowsy, low conscious state	Mirtazapine and Olanzapine
Depressed level of consciousnes	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 27/01/2004 **Stopped:** 30/01/2004

OLANZAPINE (Suspected) **Reason:** Unspecified psychosis
Tablet 1.2 Milligram Daily Oral
Batch: **Started:** 30/01/2004 **Stopped:** 30/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/05/2004	Other data				

Additional Information:

Patient was also taking Venlafaxine, Aspirin, Lactulose, Coloxyl with Senna, Ostelin, Caltrate, Diamicron, Diabex, Ranitidine, Keflex, Captopril.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 197241 **Seq:** 1 **Gender:** F
Reported: 11/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 36Y
Onset Date: 15/12/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pharyngolaryngeal pain Agranulocytosis Neutropenia Pyrexia	Caused or prolonged inpatient hospitalisation	Patient presented with sore throat and fever, neutropenia.	IV ampicillin and gentamicin,

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Batch: **Started:** 10/12/2003 **Stopped:** 17/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/05/2004	Neutrophils		17/12/2003	0.03	

Additional Information:

Patient also taking Loette, zolpiderm.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 197483 **Seq:** 1 **Gender:** M
Reported: 20/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 82
Onset Date: **DOB:** 03/05/1922
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
International normalised ratio inc Drug interaction		INR increased.	

Medicine Details:

COUMADIN (Interaction) **Reason:** Acute,ill-def cerebrovascular disease w/o hyperte
Tablet Oral
Batch: **Started:** 22/04/2004 **Stopped:** Continuing

Mirtazon (Interaction) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 03/05/2004 **Stopped:** Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/05/2004	International		28/04/2004	2.0	
20/05/2004	International		30/04/2004	2.4	
20/05/2004	International		03/05/2004	3.4	
20/05/2004	International		04/05/2004	4.3	
20/05/2004	International		05/05/2004	4.5	
20/05/2004	International		06/05/2004	5.0	
20/05/2004	International		07/05/2004	4.1	

Additional Information:

Patient also taking Megatfol, Prafachol, Natrilix SR, Karvea and Tenopt.

Report Detail

Case Number: 197483 **Seq:** 1
Reported: 20/05/2004
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 82
DOB: 03/05/1922
Causality: Causality possible

Reaction Detail

Medicine Details:

COUMADIN (Interaction)			**Reason:**	Acute,ill-def cerebrovascular disease w/o hyperte	
Tablet				Oral	
Batch:	**Started:**	22/04/2004	**Stopped:**		Continuing
Mirtazon (Interaction)			**Reason:**	Depression	
Tablet	30.0	Milligram	Daily	Oral	
Batch:	**Started:**	03/05/2004	**Stopped:**		Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/05/2004	International		09/05/2004	3.4	
20/05/2004	International		10/05/2004	2.7	

Additional Information:

Patient also taking Megatfol, Prafachol, Natrilix SR, Karvea and Tenopt.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 197592 **Seq:** 1
Reported: 26/05/2004
Hospitalisation:
Onset Date: 15/01/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 83Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Delirium Dyskinesia Rash Tremor		Agitated, shaky, confused, jerky movements, delirium and rash.	Ciprofloxacin and Mirtazepine ceased. Rash treated with Phenergan.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 19/12/2003 **Stopped:** 19/01/2004

CIPROFLOXACIN (Suspected) **Reason:** Unspecified septicemia
Tablet 1.5 Gram Daily Oral
Batch: **Started:** 06/01/2004 **Stopped:** 19/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Digoxin, Salbutamol, Ipratropium, Fludrocortisone, Potassium Chloride-Bicarbonate, Prednisolone, Omeprazole, Aspirin and Morphine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 197744 **Seq:** 1 **Gender:** F
Reported: 31/05/2004 **Weight:** 64.00
Hospitalisation: **Age:** 50
Onset Date: 17/05/2004 **DOB:** 21/03/1954
Outcome: Recovered 22/05/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain in extremity Restless legs syndrome		Within half an hour of commencing Avanza forearms ached and ached while legs became restless for hours.	Avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Acimax, Estraderm mx 100 and Oroxine. Pains repeated on each of four successive night. Allergies to Iodeine Antiseptics, Voltaren - vomits, Fluvoxamine - nausea and beestings.

Report Detail

Case Number: 197781 **Seq:** 1 **Gender:** F
Reported: 01/06/2004 **Weight:** 45.00
Hospitalisation: **Age:** 83Y
Onset Date: 14/02/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash papular Petechiae		Papular rash over all body except face. Petecheal rash over legs.	Ceased Avanza

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 30/01/2004 **Stopped:** 14/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 197966 **Seq:** 1 **Gender:** F
Reported: 08/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 06/03/2004 **DOB:** 18/11/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebral haemorrhage Cerebellar infarction Dysarthria Headache Nausea Tinnitus Vertigo Vomiting		Infarction of the cerebellum, with a minor haemorrhagic component, sudden onset of vertigo, nausea, vomiting and tinnitus, with slurred speeck and a occipital headache.	

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:**
0.0 Milligram
Batch: **Started:** **Stopped:**

REMERON (Suspected) **Reason:** Depression
Tablet 1.0 Gram Daily Oral
Batch: **Started:** 02/02/2004 **Stopped:** 06/03/2004 2 months

TRISEQUENS (Suspected) **Reason:**
Tablet 4.0 Dose Unspecified Daily Oral
Batch: **Started:** 08/01/2004 **Stopped:** 06/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: HRT treatment.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 198061 **Seq:** 1 **Gender:** M
Reported: 11/06/2004 **Weight:** 80.00
Hospitalisation: **Age:** 34
Onset Date: 29/04/2004 **DOB:** 12/06/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperlipidaemia	Required Visit to Doctor	Combined severe hyperlipidaemia.	

Medicine Details:

XANAX (Other drug) **Reason:** Anxiety neurosis
500.0 Microgram As necessary
Batch: **Started:** 24/07/2002 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 22/11/2003 **Stopped:** 29/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 198094 **Seq:** 1 **Gender:** F
Reported: 11/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 74Y
Onset Date: 06/04/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Rash maculo-papular		Rash on back only - itchy. Maculopapular - spread over body.	Calamine lotion to back. Mirtazepine ceased. No antidepressant until rash resolves

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 25/03/2004 **Stopped:** 11/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Felodopine, Prednisolone, Omoprazole, Oxycodone, Dextropropoxyphene, Paracetamol, Prochlorperazine, Metoclopramide, Lactulose, Coloxyl with Senna and Enoxaparin. History: Psoriasis. Allergies to Sulfurs, Celeberx and Plaquenil.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 198170 **Seq:** 1
Reported: 16/06/2004
Hospitalisation:
Onset Date: 06/06/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 46
DOB: 11/01/1958
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	New leg oedema despite moduretic.	Drug ceased

Medicine Details:

MODURETIC (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 11/05/2004 **Stopped:** 11/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 198262 **Seq:** 1 **Gender:** F
Reported: 18/06/2004 **Weight:** 65.00
Hospitalisation: **Age:** 53
Onset Date: 06/04/2004 **DOB:** 16/04/1950
Outcome: Recovered 14/04/2004 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry eye	Required Visit to Doctor	Dry, red, puffy eyes.	
Eye swelling	Required Visit to Doctor	Dry, red, puffy eyes.	
Ocular hyperaemia	Required Visit to Doctor	Dry, red, puffy eyes.	

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** 05/04/2004 **Stopped:** 11/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Avapro.
Symptoms recurred when Avanza reinstated a week later.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 198300 **Seq:** 1
Reported: 21/06/2004
Hospitalisation:
Onset Date: 10/06/2004
Outcome: Not yet recovered

Gender: M
Weight: 65.00
Age: 71
DOB: 18/02/1933
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Required Visit to Doctor	Acute urinary retention.	IDC given.

Medicine Details:

ZYLOPRIM (Other drug) **Reason:** Othr&unspec metabolic diseases
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 28/05/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Astrix, Tritace, Minax, Quinate and Atenex. History: Benign prostate enlargment.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 198497 **Seq:** 1 **Gender:** M
Reported: 25/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 25
Onset Date: 20/06/2004 **DOB:** 06/04/1979
Outcome: Recovered 20/06/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Required Visit to Doctor	Grand mal seizure.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous seizure 10 years ago, after taking another medication.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 198568 **Seq:** 1 **Gender:** F
Reported: 28/06/2004 **Weight:** 110.00
Hospitalisation: **Age:** 43
Onset Date: 05/06/2004 **DOB:** 02/10/1960
Outcome: Recovered without treatment 22/06/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuropathy	Required Visit to Doctor	Left ulnar neuropathy; complete loss of sensation in medial arm, forearm and 4th and 5th fingers.	Nil treatment.
Sensory loss	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 03/06/2004 **Stopped:** 09/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

First exposure to this medication.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 198730 **Seq:** 1
Reported: 05/07/2004
Hospitalisation:
Onset Date: 09/06/2004
Outcome: Not yet recovered

Gender: F
Weight: 56.00
Age: 47Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased	Required Visit to Doctor	Increased appetite, eating even when feeling full, weight gain of 3kg in 3 weeks and decreased libido.	Avanza ceased.
Increased appetite	Required Visit to Doctor		
Weight increased	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 09/06/2004 **Stopped:** 28/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Celebrex, Multi B Vitamins, Evening Primrose, Vitamin C and Black Cohash.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 198764 **Seq:** 1 **Gender:** F
Reported: 07/07/2004 **Weight:** 74.00
Hospitalisation: **Age:** 77
Onset Date: **DOB:** 18/10/1926
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome		Severe restless leg syndrome.	Avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 198918 **Seq:** 1 **Gender:** F
Reported: 12/07/2004 **Weight:** 60.00
Hospitalisation: **Age:** 99U
Onset Date: 15/06/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Required Visit to Doctor	Dizziness causing falls.	
Fall	Required Visit to Doctor		

Medicine Details:

Axit (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 04/06/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Asmol and Seretide.
198918 is seq 02 of 198869 seq 01.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199046 **Seq:** 1 **Gender:** F
Reported: 16/07/2004 **Weight:** 82.00
Hospitalisation: **Age:** 53
Onset Date: 07/07/2004 **DOB:** 28/09/1950
Outcome: Recovered 12/07/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sedation	Required Visit to Doctor	Excessive sedation and dizziness.	Zoloft ceased.
Dizziness	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram 1 time Oral
Batch: **Started:** 07/07/2004 **Stopped:** 07/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Avapro, Lipex, Celebrex, Seretide, Estraderm, Ventolin and Glucosamine.
Patient has sensitivity to Morphine and Codeine.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199122 **Seq:** 1 **Gender:** M
Reported: 19/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 14
Onset Date: 13/07/2004 **DOB:** 22/07/1989
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Flushing Muscle spasms Ocular hyperaemia Somnolence		Patient experienced fingers tingling, drowsiness, all muscle spasms in body seized up within the space of one breath - unable to move. Hot and red in face and eyes blood shot.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PANADOL (Suspected) **Reason:**
Tablet 2.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199156 **Seq:** 1 **Gender:** F
Reported: 19/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 60Y
Onset Date: 15/01/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain Gait disturbance Joint swelling		Arthralgia - intense pain and extensive swelling in knees and knuckles, back pain, pain in shoulders, neck and hip, walking difficulty.	Ceased Avanza.

Medicine Details:

AVANZA (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Lipitor, Mobic, Tramal SR.
Avanz was started and stopped sometime in Jan 2003.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199239 **Seq:** 1 **Gender:** F
Reported: 20/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: 05/12/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities Syndactyly		Foetus exposed to drug - hypoplastic left hand with all fingers fused and no thumb, three toes on both feet and a large sandal gap, talipes of the right foot, intra and perventricular haemorrhage.	Termination of pregnancy.

Medicine Details:

ELOCON (Other drug) **Reason:**
Cream 0.0 Percent Topical
Batch: **Started:** **Stopped:**

REMERON (Suspected) **Reason:** Depression
0.0 Dose Unspecified Daily
Batch: **Started:** 05/12/2003 **Stopped:** 06/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/07/2004	Other data				Antenatal untrasound at 20 weeks demonstrated absent fibula bilaterally, reduced number of toes both feet with deformity/hypoplastic left hand with syndactyly and reduced number of fingers and shortened left radius and ulna. Cleft feet. Confirmed on postmortem examination with no internal organ abnormalities normal male karyotype.

Additional Information:

Therapeutic termination of pregnancy at 20 weeks of gestation due to skeletal malformations.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199501 **Seq:** 1 **Gender:** M
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 20/08/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Violent ideation Intentional self-injury		Violent thoughts and cut himself, intentional self harm.	

Medicine Details:

MIRTAZAPINE (Suspected)		**Reason:**	
Batch:	**Started:**	**Stopped:**	0
ZOLOFT (Suspected)		**Reason:**	
Batch:	**Started:**	**Stopped:**	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199596 **Seq:** 1
Reported: 02/08/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Patient developed serotonin syndrome	Remeron discontinued
Drug interaction	Caused or prolonged inpatient hospitalisation	Possible serotonin syndrome but symptoms not described	All medications ceased. Remeron discontinued

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Interaction) **Reason:** Pain

Batch: **Started:** **Stopped:** 0

REMERON (Interaction) **Reason:**

Tablet 15.0 Milligram Daily

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Same symptoms on restarting Remeron a few days later. Again ceased and has since recovered

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199926 **Seq:** 1
Reported: 12/08/2004
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 36
DOB: 06/07/1968
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anger Agitation Social avoidant behaviour		Around day 4 patient developed increased anger and agitation and got worse - stopped at day 11. Agitation was becoming socially threatening so isolated self completely.	Counselled initiately - stopped treatment.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 29/07/2004 **Stopped:** 08/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199959 **Seq:** 1 **Gender:** M
Reported: 13/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 89
Onset Date: 01/08/2004 **DOB:** 20/02/1915
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancytopenia	Life	Drug induced pancytopaenia.	Dilantin and Mirtazepine

Medicine Details:

VENTOLIN NEBULES (Other drug) **Reason:**
Inhalation 5.0 Milligram Inhalation
Batch: **Started:** 14/07/2004 **Stopped:**

ATROVENT NEBULISING SOLUTION (Other drug) **Reason:**
Inhalation 1.0 Milligram Inhalation
Batch: **Started:** 14/07/2004 **Stopped:**

COVERSYL (Other drug) **Reason:** Congestive heart failure
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 14/07/2004

UREX (Other drug) **Reason:** Congestive heart failure
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/08/2004	Haemoglobin	130-175	23/07/2004	101	
13/08/2004	Haemoglobin	130-175	02/08/2004	100	
13/08/2004	Haemoglobin	130-175	07/08/2004	101	
13/08/2004	Platelets	150-450	23/07/2004	139	
13/08/2004	Platelets	150-450	02/08/2004	88	
13/08/2004	Platelets	150-450	07/08/2004	94	
13/08/2004	White blood cells	4.0-11.0	23/07/2004	4.7	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199959 **Seq:** 1
Reported: 13/08/2004
Hospitalisation:
Onset Date: 01/08/2004
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 89
DOB: 20/02/1915
Causality: Causality possible

Reaction Detail

Medicine Details:

FLUDROCORTISONE (Other drug)				**Reason:**	Hypotension	
Tablet	50.0	Microgram	Daily		Oral	
Batch:	**Started:**	22/07/2004		**Stopped:**		
DORYX (Other drug)				**Reason:**	Pneumonia,unspecified	
Capsule	200.0	Milligram	Daily		Oral	
Batch:	**Started:**	27/07/2004		**Stopped:**	10/08/2004	
CLAMOXYL DUO FORTE (Other drug)				**Reason:**	Pneumonia,unspecified	
Tablet	2.0	Dose Unspecified	Daily		Oral	
Batch:	**Started:**	27/07/2004		**Stopped:**	10/08/2004	
Seretide 125/25 MDI (Other drug)				**Reason:**		
Inhalation	2.0	Dose Unspecified	Daily		Inhalation	
Batch:	**Started:**	14/07/2004		**Stopped:**	0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/08/2004	White blood cells	4.0-11.0	02/08/2004	1.7	
13/08/2004	White blood cells	4.0-11.0	07/08/2004	3.9	

Additional Information:

Report Detail

Case Number: 199959 **Seq:** 1
Reported: 13/08/2004
Hospitalisation:
Onset Date: 01/08/2004
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 89
DOB: 20/02/1915
Causality: Causality possible

Reaction Detail

Medicine Details:

DILANTIN (Suspected)			**Reason:**	Convulsions		
Capsule	300.0	Milligram	Daily		Oral	
Batch:	**Started:**	31/07/2003		**Stopped:**	05/08/2004	
REMERON (Suspected)			**Reason:**	Depression		
Tablet	15.0	Milligram	Daily		Oral	
Batch:	**Started:**	22/07/2004		**Stopped:**	03/08/2004	0

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 199972 **Seq:** 1
Reported: 13/08/2004
Hospitalisation:
Onset Date: 12/04/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 89
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Agitation		Patient experienced increased confusion and agitation	Mirtazipine ceased

Medicine Details:

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep

Tablet 10.0 Milligram As necessary Oral

Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 09/04/2004 **Stopped:** 12/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a recent history of decreased oral intake and decreased mobility.

Report Detail

Case Number: 199992 **Seq:** 1 **Gender:** F
Reported: 13/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 83
Onset Date: 28/11/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon		SIADH.	Decreased dose of Mirtazipine to 15mg/nocte (28/11/02) then increased to 30mg/nocte (23/12/02) then to 15mg/nocte (23/01/2003). Persisted with Mirtazepine until 18/02/03 and monitored LEC's.

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:**
Tablet 100.0 Microgram Oral
Batch: **Started:** 28/11/2002 **Stopped:**

MORPHINE SULPHATE (Other drug) **Reason:**
6.0 Millilitre
Batch: **Started:** 28/11/2002 **Stopped:** 16/02/2003

SODIUM VALPROATE (Other drug) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 28/11/2002 **Stopped:** 04/12/2002

SORBITOL (Other drug) **Reason:**
20.0 Millilitre Daily Oral
Batch: **Started:** 28/11/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/08/2004	Sodium		03/12/2002	126	
13/08/2004	Sodium		24/02/2002	134	

Additional Information:

History of hyponatremia from Cipramil.

Report Detail

Case Number: 199992 **Seq:** 1
Reported: 13/08/2004
Hospitalisation:
Onset Date: 28/11/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 83
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

PARACETAMOL (Other drug)			**Reason:**	
Tablet	4.0 Gram		Daily	Oral
Batch:	**Started:** 28/11/2002		**Stopped:**	
PANTOPRAZOLE (Other drug)			**Reason:**	
Tablet	80.0 Milligram		Daily	Oral
Batch:	**Started:** 28/11/2002		**Stopped:**	
DOMPERIDONE (Other drug)			**Reason:**	
Tablet	30.0 Milligram		Daily	Oral
Batch:	**Started:** 28/11/2002		**Stopped:**	
MIRTAZAPINE (Suspected)			**Reason:**	Depression
Tablet	60.0 Milligram			Oral
Batch:	**Started:** 28/11/2002		**Stopped:**	18/02/2003

Laboratory Investigations:

Additional Information:

History of hyponatremia from Cipramil.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200094 **Seq:** 1 **Gender:** M
Reported: 17/08/2004 **Weight:** 95.00
Hospitalisation: **Age:** 43
Onset Date: **DOB:** 06/04/1961
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysgeusia	Required Visit to Doctor	Taste buds more sensitive.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 04/07/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200140 **Seq:** 1 **Gender:** M
Reported: 19/08/2004 **Weight:** 70.00
Hospitalisation: **Age:** 70
Onset Date: 29/07/2004 **DOB:** 27/04/1934
Outcome: Recovered 02/08/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient developed neutropanea.	Cessation of Mirtazapine.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
90.0 Milligram Daily
Batch: **Started:** 22/07/2004 **Stopped:** 30/07/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previously on Mirtazapine 15mg BD (long standing dose). Patient has known follicular lymphoma, with past history of neutropenia post chemotherapy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200170 **Seq:** 1 **Gender:** F
Reported: 20/08/2004 **Weight:** 73.00
Hospitalisation: **Age:** 99U
Onset Date: 14/07/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Increased appetite	Required Visit to Doctor	Extreme increase in appetite	Mirtazapine ceased.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 07/07/2004 S TERM **Stopped:** 14/07/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200228 **Seq:** 1
Reported: 23/08/2004
Hospitalisation:
Onset Date: 29/07/2004
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 84
DOB: 28/01/1920
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Tardive dyskinesia - oral (lipsmacking, liplicking movements)	

Medicine Details:

PARACETAMOL (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

ALODORM (Other drug) **Reason:** Specific disorders of sleep
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

MEGAFOL (Other drug) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
50.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms observed whilst taking Risperidone but has become more pronounced recently on "Axit 30" brand.

Report Detail

Case Number: 200228 **Seq:** 1
Reported: 23/08/2004
Hospitalisation:
Onset Date: 29/07/2004
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 84
DOB: 28/01/1920
Causality: Causality possible

Reaction Detail

Medicine Details:

SEROQUEL (Other drug)			**Reason:**	Unspecified psychosis	
Tablet	50.0	Milligram	Daily	Oral	
Batch:	**Started:**	15/11/2003		**Stopped:**	15/12/2003
RISPERIDONE (Other drug)			**Reason:**	Unspecified psychosis	
	1.0	Milligram	Daily		
Batch:	**Started:**	15/01/2002		**Stopped:**	15/06/2003 0
MIRTAZAPINE (Suspected)			**Reason:**	Depression	
Tablet	60.0	Milligram	Daily	Oral	
Batch:	**Started:**	15/08/2002		**Stopped:**	

Laboratory Investigations:

Additional Information:

Symptoms observed whilst taking Risperidone but has become more pronounced recently on "Axit 30" brand.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200387 **Seq:** 1 **Gender:** M
Reported: 30/08/2004 **Weight:** 92.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 23/08/2004 **DOB:** 17/12/1965
Outcome: Recovered 24/08/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Caused or prolonged inpatient hospitalisation	Patient developed acute urinary retention.	Catheterized.

Medicine Details:

AVANZA (Other drug) **Reason:**
Tablet 30.0 Milligram Daily
Batch: **Started:** 15/06/2002 **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 15/06/2002 **Stopped:** 0

SEROQUEL (Suspected) **Reason:** Unspecified psychosis
800.0 Milligram Daily
Batch: **Started:** 15/05/2003 **Stopped:** 0

Valpam (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** 15/02/2004 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 200411 **Seq:** 1 **Gender:** F
Reported: 30/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 73Y
Onset Date: 14/04/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced abnormal liver function	Avanza ceased.

Medicine Details:

ATACAND (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

NORVASC (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

METHOTREXATE (Other drug) **Reason:** Other rheumatoid arthritis
8.0 Milligram Weekly
Batch: **Started:** L TERM **Stopped:**

ARAVA (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/08/2004	ALT = SGPT		27/04/2004	161	
30/08/2004	AST = SGOT		27/04/2004	109 u/l	
30/08/2004	GGT = SGGT =		27/04/2004	32	
30/08/2004	LDH		27/04/2004	307	

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200411 **Seq:** 1 **Gender:** F
Reported: 30/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 73Y
Onset Date: 14/04/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

VIOXX (Other drug)			**Reason:**	Other rheumatoid arthritis
	25.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
PREDNISONE (Other drug)			**Reason:**	Other rheumatoid arthritis
	5.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
AVANZA (Suspected)			**Reason:**	
Batch:	**Started:**	15/03/2004		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200460 **Seq:** 1
Reported: 01/09/2004
Hospitalisation:
Onset Date: 24/08/2004
Outcome: Recovered without treatment

Gender: F
Weight: 0.00
Age: 53
DOB: 26/10/1950
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence	Required Visit to Doctor	Patient experienced severe drowsiness, confusion, staggering and nausea.	Nil
Confusional state	Required Visit to Doctor		
Gait disturbance	Required Visit to Doctor		
Nausea	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200528 **Seq:** 1 **Gender:** M
Reported: 03/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 29Y
Onset Date: 15/07/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Widespread joint pains.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200550 **Seq:** 1
Reported: 03/09/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	During treatment with Remeron she developed acute bowel obstruction which was due to acute pancreatitis.	Omeprazole
Pancreatitis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Tablet 45.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200616 **Seq:** 1
Reported: 07/09/2004
Hospitalisation:
Onset Date: 30/07/2004
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 38
DOB: 10/07/1966
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia	Required Visit to Doctor	Alopecia and acne.	Change antidepressant.
Acne	Required Visit to Doctor		

Medicine Details:

SLOW-K (Other drug) **Reason:**
Tablet 4.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

SODIBIC (Other drug) **Reason:**
Capsule 6.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet, film coated 60.0 Milligram Daily Oral
Batch: **Started:** 30/07/2004 **Stopped:** 01/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200641 **Seq:** 1
Reported: 08/09/2004
Hospitalisation: Admitted to hospital
Onset Date: 16/03/2004
Outcome: Recovered

Gender: F
Weight: 48.10
Age: 86
DOB: 31/05/1917
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged inpatient hospitalisation	Patient admitted with agitation, pressured speech and paranoia.	Mirtazapine stopped, prn Olanzapine oral/wafers.
Agitation	Caused or prolonged inpatient hospitalisation		
Paranoia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ALENDRONATE SODIUM (Other drug) **Reason:** Osteoporosis
Tablet 70.0 Milligram Weekly Oral
Batch: **Started:** L TERM **Stopped:**

METHOTREXATE (Other drug) **Reason:** Other rheumatoid arthritis
Injection 10.0 Milligram Weekly
Batch: **Started:** L TERM **Stopped:**

FOLIC ACID (Other drug) **Reason:**
Tablet 0.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

FRUSEMIDE (Other drug) **Reason:** Essential benign hypertension
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history of major depression.

Report Detail

Case Number: 200641 **Seq:** 1
Reported: 08/09/2004
Hospitalisation: Admitted to hospital
Onset Date: 16/03/2004
Outcome: Recovered

Gender: F
Weight: 48.10
Age: 86
DOB: 31/05/1917
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation		
Speech disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

METOPROLOL TARTRATE (Other drug) **Reason:** Otr&nos disord of heart rhythm
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

DIGOXIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
125.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 0

CLOPIDOGREL (Other drug) **Reason:**
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ENALAPRIL MALEATE (Other drug) **Reason:** Essential benign hypertension
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Additional Information:
Patient history of major depression.

Report Detail

Case Number: 200641 **Seq:** 1
Reported: 08/09/2004
Hospitalisation: Admitted to hospital
Onset Date: 16/03/2004
Outcome: Recovered

Gender: F
Weight: 48.10
Age: 86
DOB: 31/05/1917
Causality: Causality possible

Reaction Detail

Medicine Details:

CALCIUM CARBONATE (Other drug)			**Reason:**	Osteoporosis	
Tablet	1.0	Gram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
PREDNISOLONE (Other drug)			**Reason:**	Other rheumatoid arthritis	
	2.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
SPIRONOLACTONE (Other drug)			**Reason:**	Essential benign hypertension	
Tablet	25.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
PARACETAMOL (Other drug)			**Reason:**	Pain	
	4.0	Gram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Additional Information:

Patient history of major depression.

Report Detail

Case Number: 200641 **Seq:** 1
Reported: 08/09/2004
Hospitalisation: Admitted to hospital
Onset Date: 16/03/2004
Outcome: Recovered

Gender: F
Weight: 48.10
Age: 86
DOB: 31/05/1917
Causality: Causality possible

Reaction Detail

Medicine Details:

COLOXYL WITH SENNA (Other drug)				**Reason:**	Constipation	
Tablet	4.0	Dose Unspecified	Daily		Oral	
Batch:	**Started:**	L TERM		**Stopped:**		
OXYCONTIN (Other drug)				**Reason:**	Otr&unsp vertebrogen pain synd	
Tablet	20.0	Milligram	Daily		Oral	
Batch:	**Started:**	L TERM		**Stopped:**		
MIRTAZAPINE (Suspected)				**Reason:**	Depression	
Tablet	15.0	Milligram	Daily		Oral	
Batch:	**Started:**	11/03/2004		**Stopped:**	16/03/2004	0

Laboratory Investigations:

Additional Information:

Patient history of major depression.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200886 **Seq:** 1 **Gender:** M
Reported: 15/09/2004 **Weight:** 80.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Loss of libido	Required Visit to Doctor	Complete loss of libido.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 200923 **Seq:** 1 **Gender:** M
Reported: 16/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: 07/09/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Required Visit to Doctor	Felt 'electric shock' in elbow of left arm and knee of left leg (nocturnal).	

Medicine Details:

Mirtazon (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Alternate days Oral
Batch: **Started:** 07/08/2004 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 201079 **Seq:** 1
Reported: 23/09/2004
Hospitalisation:
Onset Date: 24/04/2004
Outcome: Death, maybe drug

Gender: F
Weight: 0.00
Age: 50
DOB: 22/06/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic steatosis Drug toxicity		Fatty liver and drug toxicity	

Medicine Details:

RISPERIDONE (Suspected) **Reason:** Unspecified schizophrenia
Injection Intramuscular
Batch: **Started:** 24/02/2004 S TERM **Stopped:** 16/04/2004 0

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

Zolpidem Sandoz (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

ZYPREXA (Suspected) **Reason:** Unspecified schizophrenia
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 18/03/2004 **Stopped:** 02/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2004	Autopsy report				Severe fatty change in liver and chronic liver disease. Severe diffuse microvesicular fatty changes throughout the liver. Lungs, heart, kidney and brain.

Additional Information:

Chronic liver disease.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201314 **Seq:** 1 **Gender:** F
Reported: 28/09/2004 **Weight:** 60.00
Hospitalisation: **Age:** 26
Onset Date: 15/08/2004 **DOB:** 21/12/1977
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema	Required Visit to Doctor	Patient experienced facial oedema.	Cessation of Mirtazapine

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/06/2004 **Stopped:** 15/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 201356 **Seq:** 1
Reported: 29/09/2004
Hospitalisation: Admitted to hospital
Onset Date: 31/05/2004
Outcome: Not yet recovered

Gender: F
Weight: 65.00
Age: 91
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Severe	Hyponatraemia.	Avanza ceased, fluid

Medicine Details:

FISH OIL NOS (Other drug)			**Reason:**		
Capsule	3.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
MULTIVITAMINS (Other drug)			**Reason:**		
Tablet			Daily		Oral
Batch:	**Started:**			**Stopped:**	
TOFRANIL (Other drug)			**Reason:**		
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
AVANZA (Suspected)			**Reason:**		
Tablet	15.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	31/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/09/2004	Other data				OSM - 254 (serum)
29/09/2004	Sodium		22/04/2004	132	
29/09/2004	Sodium		31/05/2004	118	
29/09/2004	Sodium		01/06/2004	124	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201382 **Seq:** 1 **Gender:** F
Reported: 30/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 77Y
Onset Date: 09/07/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Chest pain Headache Restless legs syndrome		Nausea, headache, chest pain, leg	Ceased Avanza

Medicine Details:

STEMETIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

DARBEPOETIN ALFA (Other drug) **Reason:**
Injection 40.0 Microgram 1 time Intravenous
Batch: **Started:** **Stopped:**

CALCITRIOL (Other drug) **Reason:**
4.0 Dose Unspecified Weekly
Batch: **Started:** **Stopped:**

LIGNOCAINE (Other drug) **Reason:**
2.5 Millilitre As necessary
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 201382 **Seq:** 1
Reported: 30/09/2004
Hospitalisation:
Onset Date: 09/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 77Y
DOB:
Causality: Causality probable

Reaction Detail

Medicine Details:

FOLIC ACID (Other drug)			**Reason:**		
Tablet	5.0	D Antigen Unit	Daily		Oral
Batch:	**Started:**			**Stopped:**	
PARACETAMOL (Other drug)			**Reason:**		
	8.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
ASPIRIN (Other drug)			**Reason:**		
Tablet	150.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
COLOXYL WITH SENNA (Other drug)			**Reason:**		
Tablet	4.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 201382 **Seq:** 1 **Gender:** F
Reported: 30/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 77Y
Onset Date: 09/07/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

CLEXANE (Other drug)			**Reason:**		
Injection	20.0	Milligram	Daily		Subcutaneous
Batch:	**Started:** 24/06/2004			**Stopped:**	
ALUMINIUM HYDROXIDE (Other drug)			**Reason:**		
Tablet	2.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
NYSTATIN (Other drug)			**Reason:**		
	4.0	Millilitre	Daily		Oral
Batch:	**Started:**			**Stopped:**	
AVANZA (Suspected)			**Reason:**		
Tablet	15.0	Milligram	1 time		Oral
Batch:	**Started:** 09/07/2004			**Stopped:**	09/07/2004

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201512 **Seq:** 1
Reported: 07/10/2004
Hospitalisation:
Onset Date: 24/09/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 87
DOB: 29/05/1917
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Rash		Patient developed an itchy rash on arms under penis and on abdomen.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 29/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201541 **Seq:** 1 **Gender:** F
Reported: 08/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 57
Onset Date: 21/09/2004 **DOB:** 16/10/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis.	

Medicine Details:

XANAX (Suspected) **Reason:**
Tablet 2.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

STILNOX (Suspected) **Reason:**
Tablet 10.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/10/2004	Other data				Autopsy "drug related, longstanding" myocarditis.

Additional Information:

Palpitations since March 2004.
Report 201542 is the second sequence to this report.

Report Detail

Case Number: 201577 **Seq:** 1
Reported: 08/10/2004
Hospitalisation: Admitted to hospital
Onset Date: 25/08/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 45
DOB: 23/09/1958
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient experienced seizures and had reported being increasingly confused, but was also post ictal	Mirtazepine ceased, patient was fluid restricted and Reboxetine commenced.
Confusional state	Caused or prolonged inpatient hospitalisation		
Inappropriate antidiuretic hormon	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CARBAMAZEPINE (Other drug) **Reason:** Other&unspecified epilepsy
Tablet 900.0 Milligram Oral
Batch: **Started:** **Stopped:**

MEDROXYPROGESTERONE ACETATE (Other drug) **Reason:** Menopausal symptoms
Tablet 2.0 Milligram Oral
Batch: **Started:** **Stopped:**

PIPERAZINE OESTRONE SULPHATE (Other drug) **Reason:** Menopausal symptoms
625.0 Microgram
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Other drug) **Reason:** Gastrojejunal ulcer w/o ment perf
Tablet 2.0 Gram Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/10/2004	Sodium		25/08/2004	123	
08/10/2004	Sodium		30/08/2004	132	

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201577 **Seq:** 1
Reported: 08/10/2004
Hospitalisation: Admitted to hospital
Onset Date: 25/08/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 45
DOB: 23/09/1958
Causality: Causality probable

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201659 **Seq:** 1 **Gender:** F
Reported: 13/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 75
Onset Date: 27/04/2004 **DOB:** 17/06/1928
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Patient developed abnormal LFTs.	All medications ceased.

Medicine Details:

LIPEX (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet Oral
Batch: **Started:** **Stopped:**

FOSAMAX (Other drug) **Reason:** Osteoporosis
Tablet Oral
Batch: **Started:** **Stopped:**

NATRILIX (Other drug) **Reason:** Essential benign hypertension
Tablet Oral
Batch: **Started:** **Stopped:**

METHOTREXATE (Suspected) **Reason:** Other rheumatoid arthritis
15.0 Milligram
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201659 **Seq:** 1
Reported: 13/10/2004
Hospitalisation:
Onset Date: 27/04/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 75
DOB: 17/06/1928
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected)		**Reason:**	
Tablet			Oral
Batch:	**Started:**		**Stopped:**
FELDENE (Suspected)		**Reason:**	Other rheumatoid arthritis
			Oral
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201752 **Seq:** 1 **Gender:** M
Reported: 15/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 13/10/2004 **DOB:** 30/03/1974
Outcome: Recovered 13/10/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Required Visit to Doctor	Severe migraine, with throbbing headache and vomiting.	Ibuprofen 400mg with easing of symptoms after half an hour.
Vomiting	Required Visit to Doctor		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet 30.0 Milligram 1 time Oral
Batch: **Started:** 13/10/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had not previously had a migraine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201849 **Seq:** 1 **Gender:** F
Reported: 20/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 25
Onset Date: 12/10/2004 **DOB:** 05/03/1979
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction		Pseudobowel obstruction.	Ceased Mirtazepine

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 11/10/2004 **Stopped:** 14/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201858 **Seq:** 1 **Gender:** F
Reported: 20/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 59Y
Onset Date: 15/08/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Memory impairment	Required Visit to Doctor	Started Avanza due to worsening of depression, felt euporic and slept well for the 1st 4 months. The last 2months, starting to have more "down days". Spelling and language skills are deteriorating, forgetting the name of acquaintances and appointments. Also has been suffering from joint pain.	
Arthralgia	Required Visit to Doctor		
Confusional state	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/02/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 201858 **Seq:** 1
Reported: 20/10/2004
Hospitalisation:
Onset Date: 15/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 59Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression	Required Visit to Doctor		
Drug ineffective	Required Visit to Doctor		
Euphoric mood	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 01/02/2004 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202053 **Seq:** 1 **Gender:** F
Reported: 26/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 48
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome Akathisia		Patient experienced restless legs and	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 27/09/2004 **Stopped:** 04/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202104 **Seq:** 1
Reported: 27/10/2004
Hospitalisation:
Onset Date: 15/10/2004
Outcome: Not yet recovered

Gender: M
Weight: 130.00
Age: 26
DOB: 13/10/1978
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction Premature ejaculation		Secondary impotence and premature	Trial of Viagra 50mg

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 90.0 Milligram Daily Oral

Batch: **Started:** 09/09/2004 **Stopped:**

NEULACTIL (Suspected) **Reason:** Unspecified psychosis

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 12/08/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202148 **Seq:** 1 **Gender:** M
Reported: 29/10/2004 **Weight:** 70.00
Hospitalisation: **Age:** 58
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence	Required Visit to Doctor	Patient experienced being drowsy with muscle aches, agitation, insomnia, drained feeling and having a metallic taste in throat.	
Agitation	Required Visit to Doctor		
Dysgeusia	Required Visit to Doctor		
Insomnia	Required Visit to Doctor		
Myalgia	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** 18/10/2004 **Stopped:** 20/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 202164 **Seq:** 1 **Gender:** F
Reported: 29/10/2004 **Weight:** 65.00
Hospitalisation: **Age:** 84
Onset Date: 01/10/2004 **DOB:** 10/09/1920
Outcome: Recovered 26/10/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Required Visit to Doctor	Patient experienced hallucinations.	Avanza ceased.

Medicine Details:

Actonel 35mg Once-a-Week Tablet (Other drug) **Reason:**
35.0 Milligram
Batch: **Started:** **Stopped:**

ZYRTEC (Other drug) **Reason:**
10.0 Millilitre Daily Oral
Batch: **Started:** L TERM **Stopped:** 0

SOMAC (Other drug) **Reason:** Other diseases of esophagus
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 0

LASIX (Other drug) **Reason:** Congestive heart failure
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 202164 **Seq:** 1 **Gender:** F
Reported: 29/10/2004 **Weight:** 65.00
Hospitalisation: **Age:** 84
Onset Date: 01/10/2004 **DOB:** 10/09/1920
Outcome: Recovered 26/10/2004 **Causality:** Causality probable

Reaction Detail

Medicine Details:

SEREPAX (Other drug)			**Reason:**	Anxiety neurosis	
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
ZANIDIP (Other drug)			**Reason:**	Essential benign hypertension	
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
LIPITOR (Other drug)			**Reason:**		
Tablet	80.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
TRITACE (Other drug)			**Reason:**	Essential benign hypertension	
	10.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202164 **Seq:** 1 **Gender:** F
Reported: 29/10/2004 **Weight:** 65.00
Hospitalisation: **Age:** 84
Onset Date: 01/10/2004 **DOB:** 10/09/1920
Outcome: Recovered 26/10/2004 **Causality:** Causality probable

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 30/07/2004 **Stopped:** 19/10/2004

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202245 **Seq:** 1
Reported: 02/11/2004
Hospitalisation:
Onset Date: 02/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 64.00
Age: 51
DOB: 27/02/1953
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Required Visit to Doctor	Abnormal LFT's	Stopped Avanza

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 0.0 Dose Unspecified Daily Oral
Batch: **Started:** 23/07/2004 **Stopped:** 17/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous exposure to this drug. Has been on Fluoxetine in the past without any problems.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202657 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 19/06/1977
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Overdose Suicidal ideation Suicide attempt		Patient experienced overdose, suicidal ideation and suicide attempt.	Discharged on Efexor x R

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202673 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

RISPERIDONE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

QUETIAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202711 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 62
Onset Date: **DOB:** 14/05/1942
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intentional self-injury		Deliberate self harm.	

Medicine Details:

AVANZA (Suspected) **Reason:**

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202748 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 58
Onset Date: **DOB:** 12/09/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt.	

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202773 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 65
Onset Date: **DOB:** 23/06/1939
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Patient had mild hypomania and a death	

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202782 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 20/08/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Suicide attempt		Suicidal ideation and suicide attempt.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

EFEXOR (Suspected) **Reason:**
300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202834 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicidal ideation and suicide attempt.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

EFEXOR (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 202909 **Seq:** 1
Reported: 22/11/2004
Hospitalisation:
Onset Date: 27/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 05/02/1931
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		The patient experienced elevated LFTs.	Observation and monitoring.

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:** Otr&nos disord of heart rhythm
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HYGROTON (Other drug) **Reason:** Essential benign hypertension
Tablet 12.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 20/07/2004 **Stopped:** 27/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/11/2004	ALT = SGPT		27/08/2004	70	
22/11/2004	GGT = SGGT =		27/08/2004	107	
22/11/2004	GGT = SGGT =		20/10/2004	149	
22/11/2004	GGT = SGGT =		10/11/2004	104	
22/11/2004	SAP = ALP		20/10/2004	143	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 202961 **Seq:** 1 **Gender:** M
Reported: 23/11/2004 **Weight:** 100.00
Hospitalisation: **Age:** 30
Onset Date: 17/10/2004 **DOB:** 06/02/1974
Outcome: Recovered 30/10/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia	Required Visit to Doctor	Polymyalgia, bilateral temporomandibular	
Temporomandibular joint syndror	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 11/10/2004 **Stopped:** 26/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 203062 **Seq:** 1
Reported: 25/11/2004
Hospitalisation: Admitted to hospital
Onset Date: 11/11/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 79
DOB: 28/11/1924
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient developed hyponatraemia.	Fluid restriction and salt tablets

Medicine Details:

ASPIRIN (Other drug) **Reason:**
100.0 Milligram Oral
Batch: **Started:** **Stopped:**

BETALOC (Other drug) **Reason:**
Tablet 50.0 Milligram Oral
Batch: **Started:** **Stopped:**

DIAZEPAM (Other drug) **Reason:**
5.0 Milligram
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 203319 **Seq:** 1 **Gender:** F
Reported: 06/12/2004 **Weight:** 71.00
Hospitalisation: **Age:** 46
Onset Date: 02/11/2004 **DOB:** 07/08/1958
Outcome: Recovered 30/11/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal distension	Required Visit to Doctor	Tense abdominal bloating and peripheral	
Oedema peripheral	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 21/10/2004 **Stopped:** 15/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 203713 **Seq:** 1 **Gender:** F
Reported: 21/12/2004 **Weight:** 90.00
Hospitalisation: **Age:** 56
Onset Date: 15/09/2004 **DOB:** 13/02/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Insomnia Psychomotor hyperactivity		Insomnia, hyperactivity for 48 hours after taking 1 Avanza tablet, persevered with it for a week, continued to have sleepless nights	Ceased Avanza

Medicine Details:

AVANZA (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Similar reaction to Nembutal years ago.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 203856 **Seq:** 1
Reported: 04/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 09/12/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 81
DOB: 21/10/1923
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Agranulocytosis and fever.	IV Antibiotics and fluid, Remeron was ceased.
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

REMERON (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** 14/10/2004 **Stopped:** 10/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/01/2005	Creatinine		13/12/2004	16.7	
04/01/2005	Neutrophils		09/12/2004	0.1	
04/01/2005	Neutrophils		13/12/2004	0.02	
04/01/2005	Urea		13/12/2004	12.5	
04/01/2005	leucocytes		09/12/2004	1.6	
04/01/2005	leucocytes		13/12/2004	3.4	

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204053 **Seq:** 1
Reported: 10/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 25/09/2004
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 88Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	The patient presented with seizure.	Tramadol ceased. Valproate 500mg bd commenced.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**
50.0 Milligram As necessary
Batch: **Started:** 23/09/2004 **Stopped:** 25/09/2004 0

MIRTAZAPINE (Interaction) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/01/2005	Other data	350-700	24/09/2004	298	Valproate level

Additional Information:

Prior CVA.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204092 **Seq:** 1 **Gender:** M
Reported: 11/01/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 32
Onset Date: 04/11/2004 **DOB:**
Outcome: Recovered 05/11/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Euphoric mood	Required Visit to Doctor	Patient experienced euphoria / mania for	Avanza ceased by patient.
Mania	Required Visit to Doctor		

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram 1 time Oral
Batch: **Started:** 04/11/2004 **Stopped:** 05/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204179 **Seq:** 1
Reported: 13/01/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Required Visit to Doctor	Ringing ears and burping.	
Eructation	Required Visit to Doctor		

Medicine Details:

Lexapro (Other drug) **Reason:**
10.0 Milligram Oral
Batch: **Started:** 18/12/2004 **Stopped:**

LIPITOR (Other drug) **Reason:**
Tablet 20.0 Milligram Oral
Batch: **Started:** 28/12/2004 **Stopped:**

XANAX (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Oral
Batch: **Started:** 01/02/2003 **Stopped:**

COVERSYL (Other drug) **Reason:**
Tablet 4.0 Milligram Oral
Batch: **Started:** 16/01/2003 **Stopped:** 24/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 204179 **Seq:** 1
Reported: 13/01/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected)		**Reason:**	
Tablet	30.0 Milligram		Oral
Batch:	**Started:** 18/07/2003	**Stopped:**	22/08/2003
AVANZA (Suspected)		**Reason:**	
Tablet	30.0 Milligram		Oral
Batch:	**Started:** 21/10/2004	**Stopped:**	16/12/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204256 **Seq:** 1
Reported: 14/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 03/12/2004
Outcome: Not yet recovered

Gender: U
Weight: 0.00
Age: 69
DOB: 25/10/1935
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	The patient experienced myocarditis, increased troponin and ejection fraction decreased	Olanzapine ceased, ACE inhibitors, supportive.
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Unspecified schizophrenia
10.0 Milligram Daily
Batch: **Started:** 22/11/2004 **Stopped:** 03/12/2004

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 15/01/2004 **Stopped:** 03/12/2004

KEFLEX (Suspected) **Reason:** Othr diseases of urinary tract
2.0 Milligram Daily Oral
Batch: **Started:** 24/11/2004 **Stopped:** 07/12/2004

HALOPERIDOL (Suspected) **Reason:** Otr spec symp psychopathol nec
2.0 Milligram Daily
Batch: **Started:** 22/11/2004 **Stopped:** 07/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2005	Other data				LV impariment EF 30%
14/01/2005	Troponin				troponin rised 4.4

Additional Information:

Report Detail

Case Number: 204312 **Seq:** 1
Reported: 18/01/2005
Hospitalisation:
Onset Date: 25/10/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 38
DOB: 11/10/1966
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Severe tight oedema to above knees.	

Medicine Details:

METHADONE HYDROCHLORIDE (Other drug) **Reason:** Depend on opium,opm alkl&deriv
50.0 Milligram Daily Oral
Batch: **Started:** 01/02/2002 **Stopped:**

REMERON (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 15/09/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204401 **Seq:** 1 **Gender:** M
Reported: 21/01/2005 **Weight:** 0.00
Hospitalisation: **Age:** 81
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia.	Mirtazapine discontinued.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204408 **Seq:** 1
Reported: 21/01/2005
Hospitalisation:
Onset Date:
Outcome: Recovered with sequelae

Gender: F
Weight: 0.00
Age: 73
DOB: 01/03/1931
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Gait disturbance		Patient knocked out, woke up stagger.	Mirtazapine ceased.

Medicine Details:

ZANTAC (Other drug) **Reason:**
300.0 Milligram Oral
Batch: **Started:** **Stopped:**

KALMA (Other drug) **Reason:**
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

THYROXINE SODIUM (Other drug) **Reason:**
Tablet 100.0 Microgram Daily Oral
Batch: **Started:** L TERM **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204473 **Seq:** 1 **Gender:** M
Reported: 22/01/2005 **Weight:** 78.00
Hospitalisation: **Age:** 85
Onset Date: 08/11/2004 **DOB:** 09/07/1919
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkalaemia	Required Visit to Doctor	The patient developed hyperkalaemia after commencement of Avanza.	Avanza ceased.

Medicine Details:

ASPIRIN (Other drug) **Reason:**
100.0 Milligram
Batch: **Started:** **Stopped:**

DIAMICRON (Other drug) **Reason:**
Tablet 160.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

LASIX (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

SALAZOPYRIN (Other drug) **Reason:**
2.0 Gram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2005	Potassium				6.8mmol/L. Normalised after Avanza ceased.

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204473 **Seq:** 1
Reported: 22/01/2005
Hospitalisation:
Onset Date: 08/11/2004
Outcome: Recovered

Gender: M
Weight: 78.00
Age: 85
DOB: 09/07/1919
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:**

Tablet	30.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204633 **Seq:** 1
Reported: 25/01/2005
Hospitalisation:
Onset Date: 25/10/2004
Outcome: Not yet recovered

Gender: M
Weight: 100.00
Age: 62
DOB: 13/04/1942
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Required Visit to Doctor	The patient suffered bilateral tinnitus, contant, worse in quite settings.	Ceased Mirtazapine.

Medicine Details:

LOSEC (Other drug) **Reason:** Other diseases of esophagus
40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PANAMAX (Other drug) **Reason:** Unspecified arthritis
Tablet 1.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 20/10/2004 **Stopped:** 10/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Is definitive that he had not tinnitus prior to taking mirtazapine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204765 **Seq:** 1
Reported: 01/02/2005
Hospitalisation:
Onset Date: 27/12/2004
Outcome: Not yet recovered

Gender: F
Weight: 80.00
Age: 48
DOB: 16/08/1956
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Patient took 1 x Mirtazon tablet and slept for 22 hours, patient was so drowsy, unable to work for 2 weeks.	Rang doctor, ceased Mirtazan.

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:**
8.0 Dose Unspecified
Batch: **Started:** **Stopped:**

LIPITOR (Other drug) **Reason:**
80.0 Milligram
Batch: **Started:** **Stopped:**

DIAFORMIN (Other drug) **Reason:**
850.0 Milligram
Batch: **Started:** **Stopped:**

KARVEZIDE 300/12.5 (Other drug) **Reason:**
1.0 Dose Unspecified
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 204765 **Seq:** 1
Reported: 01/02/2005
Hospitalisation:
Onset Date: 27/12/2004
Outcome: Not yet recovered

Gender: F
Weight: 80.00
Age: 48
DOB: 16/08/1956
Causality: Causality possible

Reaction Detail

Medicine Details:

TRITACE (Other drug)			**Reason:**	
	2.0 Milligram			
Batch:	**Started:**		**Stopped:**	
Seretide 250/25 MDI (Other drug)			**Reason:**	
Inhalation				Inhalation
Batch:	**Started:**		**Stopped:**	
Mirtazon (Suspected)			**Reason:**	
Tablet	30.0 Milligram	Daily		Oral
Batch:	**Started:** 27/12/2004		**Stopped:** 03/01/2005	0

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204832 **Seq:** 1
Reported: 02/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 08/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 23/03/1931
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation	Stood up suddenly lost conciousness falling down again. LOC approx 1 minute. .	Ceased
Syncope	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RANITIDINE (Other drug) **Reason:**
Tablet 150.0 Milligram Oral
Batch: **Started:** **Stopped:**

ATORVASTATIN (Other drug) **Reason:**
Tablet 10.0 Milligram Oral
Batch: **Started:** **Stopped:**

IRBESARTAN-HYDROCHLOROTHIAZIDE (Other drug) **Reason:**
1.0 Dose Unspecified
Batch: **Started:** **Stopped:**

PREDNISOLONE (Other drug) **Reason:**
Tablet 5.0 Milligram Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 204832 **Seq:** 1
Reported: 02/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 08/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 23/03/1931
Causality: Causality possible

Reaction Detail

Medicine Details:

FLUOROMETHOLONE (Other drug)			**Reason:**		
Eye Drops	1.0	Dose Unspecified			Ophthalmic
Batch:	**Started:**			**Stopped:**	
Bimatoprost (Other drug)			**Reason:**		
Eye Drops	1.0	Dose Unspecified			Ophthalmic
Batch:	**Started:**			**Stopped:**	
BRINZOLAMIDE (Other drug)			**Reason:**		
Eye Drops	3.0	Dose Unspecified			Ophthalmic
Batch:	**Started:**			**Stopped:**	
AVANZA (Suspected)			**Reason:**	Depression	
Tablet	30.0	Milligram	1 time		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204832 **Seq:** 1
Reported: 02/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 08/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 23/03/1931
Causality: Causality possible

Reaction Detail

Medicine Details:

DUCENE (Suspected) **Reason:** Anxiety neurosis

Tablet	5.0	Milligram	1 time	Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 204884 **Seq:** 1 **Gender:** F
Reported: 03/02/2005 **Weight:** 77.00
Hospitalisation: **Age:** 99U
Onset Date: 01/01/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Joint swelling	Required Visit to Doctor	Swelling of ankles.	

Medicine Details:

Mirtazon (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 25/12/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 205155 **Seq:** 1 **Gender:** M
Reported: 10/02/2005 **Weight:** 70.00
Hospitalisation: **Age:** 71
Onset Date: 15/08/2004 **DOB:** 09/12/1932
Outcome: Recovered 19/08/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema Lip swelling Throat irritation		The patient suffered angioedema - lip swelling and throat discomfort.	Symptomatic. Mirtazapine

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:** Otr peripheral vasculr disease
Tablet Oral
Batch: **Started:** **Stopped:**

TRITACE (Other drug) **Reason:** Congestive heart failure
10.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 11/08/2004 **Stopped:** 15/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 205158 **Seq:** 1
Reported: 10/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 24/10/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 81
DOB: 04/01/1923
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pitting oedema	Caused or prolonged inpatient hospitalisation	The patient experienced a pitting lower leg [illegible]	Patient was started on Lasix (as oedema was thought to be secondary to CCF), Warfarin and Clexane given

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

LASIX (Suspected) **Reason:** Edema and dropsy
Batch: **Started:** **Stopped:** 0

WARFARIN SODIUM (Suspected) **Reason:** Edema and dropsy
Tablet Oral
Batch: **Started:** **Stopped:** 0

CLEXANE (Suspected) **Reason:** Edema and dropsy
Injection
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pre-existing conditions: anaemia, hypercholesterolaemia, dementia and hypertension.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 205158 **Seq:** 1
Reported: 10/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 24/10/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 81
DOB: 04/01/1923
Causality: Causality possible

Reaction Detail

Medicine Details:

EFEXOR-XR (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 21/10/2004 **Stopped:**

Laboratory Investigations:

Additional Information:

Pre-existing conditions: anaemia, hypercholesterolaemia, dementia and hypertension.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 205407 **Seq:** 1
Reported: 21/02/2005
Hospitalisation:
Onset Date: 07/02/2005
Outcome: Recovered without treatment

Gender: F
Weight: 0.00
Age: 66
DOB: 07/04/1938
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sedation	Treated in outpatient department only	Significant sedation after taking mirtazapine 15 mg at night, with reported lethargy and weakness the following day.	Cessation of medication, ongoing review of mental state.
Asthenia	Treated in outpatient department only		
Lethargy	Treated in outpatient department only		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Tablet 15.0 Milligram 1 time Oral

Batch: **Started:** 07/02/2005 **Stopped:** 08/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 205515 **Seq:** 1
Reported: 24/02/2005
Hospitalisation:
Onset Date: 13/01/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 49
DOB: 14/02/1955
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Swelling		The patient experienced swelling of both lower limbs, abdomen and some in the	Analgesia and elevation of affected limbs.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 14/12/2004 **Stopped:** 13/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 205559 **Seq:** 1
Reported: 25/02/2005
Hospitalisation:
Onset Date: 15/12/2004
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 44
DOB: 11/04/1960
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paralysis	Required Visit to Doctor	Unable to move, irritablity, weight gain.	Ceased Avanza.
Irritability	Required Visit to Doctor		
Weight increased	Required Visit to Doctor		

Medicine Details:

EPILIM E.C. 200 (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** 27/05/2004 **Stopped:**

SEROQUEL (Other drug) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 09/12/2004 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 205924 **Seq:** 1 **Gender:** M
Reported: 10/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hemianopia	Required Specialist Consultation	The patient gradually developed a visual field defect diagnosed as homonymous hemianopia	
Visual field defect	Required Specialist Consultation		

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 90.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been on Remeron for approximately 4 years. Gradually (over the last 12 to 18 months) he developed a visual field defect diagnosed as homonymous hemianopia. His ophthalmologist could find no cause for the defect. There is no evidence of raised intraocular pressure.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 205992 **Seq:** 1 **Gender:** F
Reported: 14/03/2005 **Weight:** 71.50
Hospitalisation: **Age:** 71
Onset Date: **DOB:** 04/07/1933
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Pain in extremity		The patient developed wrist and finger joint pain 4-5 days after initiation of treatment.	

Medicine Details:

ATACAND (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
TEMAZE (Other drug)		**Reason:**	Specific disorders of sleep
Batch:	**Started:**		**Stopped:**
LOSEC (Other drug)		**Reason:**	Other diseases of esophagus
Batch:	**Started:**		**Stopped:**
ASTRIX 100 (Other drug)		**Reason:**	Asthma
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rechallanged with avanza has resulted in same pain.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 205992 **Seq:** 1
Reported: 14/03/2005
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: F
Weight: 71.50
Age: 71
DOB: 04/07/1933
Causality: Causality certain

Reaction Detail

Medicine Details:

PULMICORT (Other drug)		**Reason:**	Asthma
Batch:	**Started:**		**Stopped:**
VENTOLIN (Other drug)		**Reason:**	Asthma
Batch:	**Started:**		**Stopped:**
AVANZA (Suspected)		**Reason:**	Depression
Tablet	15.0 Milligram	Daily	Oral
Batch:	**Started:** 05/02/2005		**Stopped:** 28/02/2005

Laboratory Investigations:

Additional Information:

Rechallanged with avanza has resulted in same pain.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 206030 **Seq:** 1
Reported: 15/03/2005
Hospitalisation:
Onset Date: 14/02/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 27
DOB: 24/03/1977
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Incapacity/disability	The patient experienced extreme pain in the back of his knee. He is unable to straighten his leg and his knee is 'clicking'.	

Medicine Details:

REMERON (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: 680067/712470 **Started:** 20/01/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 206150 **Seq:** 1
Reported: 17/03/2005
Hospitalisation: Admitted to hospital
Onset Date: 21/02/2005
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 71
DOB: 17/01/1934
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Febrile neutropenia	Life		
Leukopenia	Life		
Agranulocytosis	Life	Agranulocytosis secondary to mirtazapine. Patient presented to hospital with febrile neutropenia after 20 days of mirtazapine. no past history of haematological disorders	Cefpirome, vancomycin, filgrastin (22/02 to 26/02/2005)
Hypotension	Life	On admission, temp. 40degrees, hypotension, agranulocytosis.	Cefpirome, vancomycin, filgrastin (22/02 to 26/02/2005)
Cellulitis	Life	Significant cellulitis on left upper arm also present (due to nicotine patch	Cefpirome, vancomycin, filgrastin (22/02 to 26/02/2005)
Pyrexia	Life	temp. 40degrees	Cefpirome, vancomycin, filgrastin (22/02 to 26/02/2005)

Medicine Details:

CEFUROXIME AXETIL (Other drug) **Reason:**

Tablet 250.0 Milligram Oral

Batch: **Started:** 25/01/2005 **Stopped:** 08/02/2005

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram 1 time Oral

Batch: **Started:** 02/02/2005 **Stopped:** 20/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/03/2005	Haematology				22/02 Blood film- agranulocytosis no blasts, monocytes 0, lymphocytes 0, neutrophils 0, WCC 0.1 (see supporting documents) Blood cultures:- negative

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 206159 **Seq:** 1 **Gender:** F
Reported: 17/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: **DOB:** 05/09/1980
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		The patient's prolactin levels increased.	Treated with Cabergoline. All medications ceased except Methadone.

Medicine Details:

METHADONE HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:** Change in voice
Oral
Batch: **Started:** 01/11/2004 **Stopped:** 17/12/2005 0

SODIUM VALPROATE (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:** 0

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/03/2005	Prolactin		17/11/2004	8034	
17/03/2005	Prolactin		20/12/2004	112	

Additional Information:

It is unknown how long the patient was receiving Olanzapine before she experienced elevated prolactin levels. All medications were ceased except Methadone and the prolactine levels returned to normal.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 206159 **Seq:** 1
Reported: 17/03/2005
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 24
DOB: 05/09/1980
Causality: Causality possible

Reaction Detail

Medicine Details:

DIAZEPAM (Suspected)		**Reason:**	
Batch:	**Started:**	**Stopped:**	0
TEMAZEPAM (Suspected)		**Reason:**	
			Oral
Batch:	**Started:**	**Stopped:**	0
CAMPRAL (Suspected)		**Reason:**	
Tablet			Oral
Batch:	**Started:**	**Stopped:**	0

Laboratory Investigations:

Additional Information:

It is unknown how long the patient was receiving Olanzapine before she experienced elevated prolactin levels. All medications were ceased except Methadone and the prolactine levels returned to normal.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 206279 **Seq:** 1 **Gender:** F
Reported: 24/03/2005 **Weight:** 78.00
Hospitalisation: **Age:** 34
Onset Date: 13/03/2005 **DOB:** 12/02/1971
Outcome: Recovered 14/03/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations Dry mouth Panic attack		PALPITATIONS DEVELOPING INTO PANIC ATTACK, DRY MOUTH-REACTION STARTING 4 DAYS AFTER COMMENCING TREATMENT WITH REDUCTIL (SEE BELOW). - SUSPECT INTERACTION BETWEEN REDUCTIL &	SETTLED WITH BED-REST AND CESSATION OF REDUCTIL

Medicine Details:

XANAX (Other drug) **Reason:**
Tablet 0.0 Milligram Oral
Batch: **Started:** 09/08/2004 **Stopped:**

REDUCTIL (Suspected) **Reason:** Obesity othr than endoc origin
Capsule 10.0 Milligram Daily Oral
Batch: ? **Started:** 09/03/2005 **Stopped:** 13/03/2005 0

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 19/01/2005 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 206281 **Seq:** 1 **Gender:** F
Reported: 28/03/2005 **Weight:** 54.00
Hospitalisation: **Age:** 15
Onset Date: 03/11/2004 **DOB:** 21/06/1989
Outcome: Recovered 06/11/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	Attempted suicide by overdose of Panadol. Frequent self harming also while on drug.	She was in hospital at time of attempt...for eating disorder. She was given charcoal, and drug to break down the paracetamol by drip.
Drug ineffective	Life		
Self injurious behaviour	Life		

Medicine Details:

RISPERIDONE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANADOL (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet Daily Oral
Batch: **Started:** 06/09/2004 **Stopped:** 06/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 206464 **Seq:** 1 **Gender:** F
Reported: 01/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 63
Onset Date: 24/12/2004 **DOB:** 13/08/1941
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Increased appetite		Increased appetitie.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 21/12/2004 **Stopped:** 24/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 206623 **Seq:** 1 **Gender:** F
Reported: 04/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 3
Onset Date: **DOB:** 30/10/2001
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Developmental delay		Mother was on Avanza during the second and third trimester of pregnancy and during breast feeding for 7 months after birth. Child has shown signs of delayed development, approximately 12 months by the age of 3 yrs old. Crawling delayed until 12 months old. Walking delayed until approximately 16 months. Speech and comprehension assessed to have a moderate delay equivalent to between 6 to 12 months	

Medicine Details:

AVANZA (Suspected) **Reason:**

Tablet 45.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207010 **Seq:** 1 **Gender:** M
Reported: 14/04/2005 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 35Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred Ocular discomfort		Patient experienced aggravated right visual blurring and visual discomfort overnight. Symptoms were occurring about every other day	Mirtazapine ceased, changed to Sertraline.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Bilateral acute angle closure caused by supraciliary effusions associated with Venlafaxine intake. Maria Hannah Pia de Guzman, Sureka Thiagalingam, Poh Yan Ong and Ivan Goldberg. MJA 2005; 782 (3): 121-123. Over the previous 2 years, similar episodes had occurred, mostly at night or in dim lighting, affecting one eye at a time and resolving spontaneously each time. The patient was not using any type of medication at the time when the episodes began to occur. Although infrequent initially, these episodes had increased to two or three times a week after Mirtazapine, a tetracyclic antidepressant, had been prescribed for depression and anxiety 5 months previously. Symptoms persisted despit treatment being changed to Sertraline, a selective serotoin reuptake

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207100 **Seq:** 1 **Gender:** F
Reported: 15/04/2005 **Weight:** 70.00
Hospitalisation: **Age:** 22Y
Onset Date: 30/03/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restlessness Drug therapy changed Insomnia		Patient switched from Avanza 30mg to Mirtazon 30mg and reported "feeling different", patient experienced restlessness and was unable to sleep	Changed drug brand back to Avanza, ceasd Mirtazon.

Medicine Details:

MERSYNDOL (Other drug) **Reason:**
1.0 Dose Unspecified
Batch: **Started:** 22/09/2004 **Stopped:**

Mirtazon (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 30/03/2005 **Stopped:** 05/04/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Selemite B tablets.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207315 **Seq:** 1 **Gender:** F
Reported: 20/04/2005 **Weight:** 65.00
Hospitalisation: Required a visit to the doctor **Age:** 54
Onset Date: 08/12/2004 **DOB:** 31/01/1950
Outcome: Recovered 06/04/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased Platelet count decreased		Leucopenia and thrombocytopenia.	Mirtazapine ceased.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Specific disorders of sleep
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 15/08/2004 **Stopped:** 10/03/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/04/2005	Neutrophils				1.6
20/04/2005	Platelets				116
20/04/2005	White blood cells				3.7

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207325 **Seq:** 1 **Gender:** M
Reported: 21/04/2005 **Weight:** 66.00
Hospitalisation: **Age:** 91
Onset Date: 11/04/2005 **DOB:** 07/11/1913
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Jaundice Pyrexia		The patient became febrile and jaundiced and his LFTs were noticed to be markedly abnormal with predominantly cholestatic picture	Augmentin Duo Forte and Mirtazapine ceased. Given antibiotic

Medicine Details:

DIGOXIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
Tablet 62.0 Microgram Daily Oral
Batch: **Started:** 18/03/2005 **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:** Constipation
Tablet 4.0 Dose Unspecified Daily Oral
Batch: **Started:** 23/03/2005 **Stopped:** 15/04/2005

ASASANTIN SR (Other drug) **Reason:** Transient cereb isch no hypert
Capsule 2.0 Dose Unspecified Daily Oral
Batch: **Started:** 18/03/2005 **Stopped:**

AUGMENTIN DUO FORTE (Suspected) **Reason:** Othr diseases of urinary tract
Tablet 2.0 Dose Unspecified Daily Oral
Batch: **Started:** 05/04/2005 **Stopped:** 11/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/04/2005	Other data				CT Abdomen showed marked intra-hepatic bile duct dilatation (1.2cm) without obvious obstructing lesion (previous cholecystectomy) and some bibasal pulmonary atalectasis.

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207325 **Seq:** 1
Reported: 21/04/2005
Hospitalisation:
Onset Date: 11/04/2005
Outcome: Not yet recovered

Gender: M
Weight: 66.00
Age: 91
DOB: 07/11/1913
Causality: Causality possible

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Otr spec symp psychopathol nec

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 08/04/2005 **Stopped:** 11/04/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207366 **Seq:** 1 **Gender:** M
Reported: 22/04/2005 **Weight:** 80.00
Hospitalisation: **Age:** 61
Onset Date: 02/04/2005 **DOB:** 08/08/1943
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Asthenia		paraesthesia and weakness starting right hand then left hand and both feet, progressing up all limbs to ;pont where patient could not stand, or even grip a cup	Cease mirtazepine

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Tablet 45.0 Milligram Daily Oral

Batch: 680067 **Started:** 01/04/2005 **Stopped:** 03/04/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207410 **Seq:** 1 **Gender:** M
Reported: 27/04/2005 **Weight:** 60.00
Hospitalisation: **Age:** 90Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Confusional state Tremor		Serotonine syndrome. Patient had sweating, confusion and mild tremor.	

Medicine Details:

SIMVASTATIN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
IMDUR (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
FRUSEMIDE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
SLOW-K (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 207410 **Seq:** 1 **Gender:** M
Reported: 27/04/2005 **Weight:** 60.00
Hospitalisation: **Age:** 90Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

TEMAZEPAM (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
TAMOXIFEN CITRATE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
TRAMAL SR (Suspected)		**Reason:**	
	100.0 Milligram		
Batch:	**Started:**		**Stopped:**
MIRTAZAPINE (Suspected)		**Reason:**	
Tablet			Oral
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207896 **Seq:** 1 **Gender:** M
Reported: 17/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 76Y
Onset Date: 01/03/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation	The patient became agitated, drowsy, vomited, experienced hallucinations, confusion, haematemesis and malaena.	Mirtazapine ceased.
Confusional state	Caused or prolonged inpatient hospitalisation		
Haematemesis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATORVASTATIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

METOPROLOL TARTRATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FOSINOPRIL-HYDROCHLOROTHIAZIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

OMEPRAZOLE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Admission notes indicate patient was often already confused with occasional hallucinations and patient has history of peptic ulcer. Efexor XR 75mg daily recently ceased (according to pharmacy last despensed 06/02/05, unsure of when patient stopped taking it).

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207896 **Seq:** 1 **Gender:** M
Reported: 17/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 76Y
Onset Date: 01/03/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Caused or prolonged inpatient hospitalisation		
Melaena	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CALTRATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FOLIC ACID (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

MIXTARD 30/70 (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AMLODIPINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Admission notes indicate patient was often already confused with occasional hallucinations and patient has history of peptic ulcer. Efexor XR 75mg daily recently ceased (according to pharmacy last despensed 06/02/05, unsure of when patient stopped taking it).

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207896 **Seq:** 1 **Gender:** M
Reported: 17/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 76Y
Onset Date: 01/03/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ACTILAX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

OSTELIN 1000 (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 28/02/2005 **Stopped:**

WARFARIN SODIUM (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Admission notes indicate patient was often already confused with occasional hallucinations and patient has history of peptic ulcer. Efexor XR 75mg daily recently ceased (according to pharmacy last despensed 06/02/05, unsure of when patient stopped taking it).

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207896 **Seq:** 1
Reported: 17/05/2005
Hospitalisation:
Onset Date: 01/03/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 76Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Suspected) **Reason:**

75.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Admission notes indicate patient was often already confused with occasional hallucinations and patient has history of peptic ulcer. Efexor XR 75mg daily recently ceased (according to pharmacy last despensed 06/02/05, unsure of when patient stopped taking it).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 207913 **Seq:** 1 **Gender:** F
Reported: 17/05/2005 **Weight:** 39.00
Hospitalisation: **Age:** 62
Onset Date: 04/04/2005 **DOB:** 07/05/1942
Outcome: Recovered 12/04/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Life [illegible]	The patient developed agranulocytosis - her neutrophil count dropped to zero.	Neupogen given.

Medicine Details:

SERETIDE ACCUHALER NOS (Other drug) **Reason:** Asthma
Batch: **Started:** **Stopped:**

ASPIRIN (Other drug) **Reason:** Acute,ill-def cerebrovascular disease w/o hyperte
100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 30/01/2005 **Stopped:** 04/04/2005

EFEXOR-XR (Suspected) **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
Batch: **Started:** 16/02/2005 **Stopped:** 04/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/05/2005	Bone marrow				Consistent with drug effect.

Additional Information:

Report Detail

Case Number: 207913 **Seq:** 1 **Gender:** F
Reported: 17/05/2005 **Weight:** 39.00
Hospitalisation: **Age:** 62
Onset Date: 04/04/2005 **DOB:** 07/05/1942
Outcome: Recovered 12/04/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

OLANZAPINE (Suspected)			**Reason:**	Depression	
	5.0	Milligram	Daily		
Batch:	**Started:**	22/02/2005		**Stopped:**	04/04/2005
LOSEC (Suspected)			**Reason:**		
	20.0	Milligram	Daily		
Batch:	**Started:**	L TERM		**Stopped:**	04/04/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208059 **Seq:** 1 **Gender:** M
Reported: 20/05/2005 **Weight:** 62.00
Hospitalisation: **Age:** 83
Onset Date: 29/04/2005 **DOB:** 06/07/1921
Outcome: Recovered 04/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Caused or prolonged inpatient hospitalisation	Urinary retention.	IDC for four days. Patient tolerated removal and recovered

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 29/03/2005 **Stopped:** 29/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208248 **Seq:** 1
Reported: 30/05/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 18/11/2004
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 38
DOB: 01/02/1966
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia		The patient developed neutropenia whilst taking Mirtazapine.	Mirtazapine ceased.

Medicine Details:

PARIET (Other drug) **Reason:** Other diseases of esophagus
20.0 Milligram
Batch: **Started:** 21/11/2003 **Stopped:**

Symbicort Turbuhaler (Other drug) **Reason:** Asthma
Inhalation 2.0 Dose Unspecified Inhalation
Batch: **Started:** 19/04/2004 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 08/11/2004 **Stopped:** 22/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/05/2005	Neutrophils		07/05/2002	2.10	
30/05/2005	Neutrophils		18/11/2004	0.95	
30/05/2005	White blood cells		07/05/2002	4.6	
30/05/2005	White blood cells		18/11/2004	3.3	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208473 **Seq:** 1 **Gender:** F
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 18
Onset Date: **DOB:** 23/11/1986
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression	Caused or prolonged inpatient hospitalisation	The patient developed borderline traits, sudden suicidal thoughts, outbursts of violence against her boyfriend, smashed furniture and could not sleep. She cleaned the house at night, her sexual desire was absent and she experienced aggression and homicidal ideation - 'cut him up and feed him to the pigs'.	
Homicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Suspected) **Reason:** Specific disorders of sleep

Tablet 5.0 Milligram As necessary Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208473 **Seq:** 1 **Gender:** F
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 18
Onset Date: **DOB:** 23/11/1986
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Caused or prolonged inpatient hospitalisation		
Suicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Suspected) **Reason:** Specific disorders of sleep

Tablet 5.0 Milligram As necessary Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208608 **Seq:** 1
Reported: 09/06/2005
Hospitalisation: Admitted to hospital
Onset Date: 19/05/2005
Outcome: Recovered

Gender: F
Weight: 79.00
Age: 32
DOB: 11/02/1973
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	The patient experienced sudden onset grand mal seizure, lasting 60 seconds and causing unconsciousness. She had post-episode confusion and amnesia.	Observation and withdrawal of medication.
Amnesia	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
Tablet — As necessary — Oral
Batch: **Started:** L TERM **Stopped:**

XANAX (Other drug) **Reason:** Anxiety neurosis
Tablet — 2.0 Milligram — Daily — Oral
Batch: **Started:** 24/06/2004 **Stopped:** 0

AVANZA (Suspected) **Reason:** Depression
Tablet — 30.0 Milligram — Daily — Oral
Batch: **Started:** 05/05/2005 **Stopped:** 10/05/2005

PROTHIADEN (Suspected) **Reason:** Depression
225.0 Milligram — Daily — Oral
Batch: **Started:** 04/11/2004 **Stopped:** 19/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208608 **Seq:** 1
Reported: 09/06/2005
Hospitalisation: Admitted to hospital
Onset Date: 19/05/2005
Outcome: Recovered

Gender: F
Weight: 79.00
Age: 32
DOB: 11/02/1973
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
Tablet — As necessary — Oral
Batch: **Started:** L TERM **Stopped:**

XANAX (Other drug) **Reason:** Anxiety neurosis
Tablet — 2.0 Milligram — Daily — Oral
Batch: **Started:** 24/06/2004 **Stopped:** 0

AVANZA (Suspected) **Reason:** Depression
Tablet — 30.0 Milligram — Daily — Oral
Batch: **Started:** 05/05/2005 **Stopped:** 10/05/2005

PROTHIADEN (Suspected) **Reason:** Depression
225.0 Milligram — Daily — Oral
Batch: **Started:** 04/11/2004 **Stopped:** 19/05/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208661 **Seq:** 1 **Gender:** F
Reported: 10/06/2005 **Weight:** 38.00
Hospitalisation: Admitted to hospital **Age:** 79
Onset Date: 23/05/2005 **DOB:** 24/04/1926
Outcome: Recovered 27/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Patient experienced confusion, fall, electrolyte imbalance and hypokalaemia.	
Fall	Caused or prolonged inpatient hospitalisation		
Hypokalaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

NATRILIX SR (Suspected) **Reason:**
Tablet 1.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/05/2005 0

MIRTAZAPINE (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/06/2005	Chloride				Cl 79.
10/06/2005	Potassium				K+ 3.2.
10/06/2005	Serum osmolality	275-300			SerOsm 245.
10/06/2005	Sodium				Na+ 119.

Additional Information:

Report Detail

Case Number: 208661 **Seq:** 1 **Gender:** F
Reported: 10/06/2005 **Weight:** 38.00
Hospitalisation: Admitted to hospital **Age:** 79
Onset Date: 23/05/2005 **DOB:** 24/04/1926
Outcome: Recovered 27/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

NATRILIX SR (Suspected) **Reason:**
Tablet 1.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/05/2005 0

MIRTAZAPINE (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208682 **Seq:** 1 **Gender:** F
Reported: 14/06/2005 **Weight:** 78.00
Hospitalisation: **Age:** 46
Onset Date: 15/05/2005 **DOB:** 30/11/1958
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome		Patient experienced severe restless leg	Diazepam and Clonazepam. Ceased Avanza.

Medicine Details:

EDRONAX (Other drug) **Reason:**
Tablet 8.0 Milligram Oral
Batch: **Started:** **Stopped:**

ZOTON (Other drug) **Reason:**
2.0 Dose Unspecified
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug positive rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208683 **Seq:** 1 **Gender:** F
Reported: 14/06/2005 **Weight:** 90.00
Hospitalisation: **Age:** 54
Onset Date: 20/05/2005 **DOB:** 18/10/1950
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome Sleep disorder		Patient complained of restless leg syndrome, she described getting restless leg syndrome about one hour after taking her evening medication. It was so severe that it was keeping her awake all night.	Clonazepam

Medicine Details:

ZYPREXA (Other drug) **Reason:**
10.0 Milligram
Batch: **Started:** **Stopped:**

EPILIM (Other drug) **Reason:**
800.0 Milligram
Batch: **Started:** 14/02/2005 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 15/07/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208696 **Seq:** 1
Reported: 15/06/2005
Hospitalisation:
Onset Date:
Outcome: Death, maybe drug

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	Patient was commenced on Remeron while an inpatient and was subsequently discharged on the drug, he suicided 3 days after discharge	

Medicine Details:

REMERON (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 208815 **Seq:** 1 **Gender:** M
Reported: 20/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 66
Onset Date: 15/04/2005 **DOB:** 17/06/1938
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mood altered		Patient had a violent mood swing, screamed at his partner and little things	Ceased Avanza.

Medicine Details:

LIPITOR (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ALPHA-TOCOPHEROL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CENOVIS MULTIVITAMIN & MINERALS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FISH OIL NOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 208815 **Seq:** 1
Reported: 20/06/2005
Hospitalisation:
Onset Date: 15/04/2005
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 66
DOB: 17/06/1938
Causality: Causality probable

Reaction Detail

Medicine Details:

GINKGO BILOBA (Other drug)			**Reason:**		
Batch:	**Started:**			**Stopped:**	
AVANZA (Suspected)			**Reason:**	Depression	
Tablet	15.0	Milligram	Daily	Oral	
Batch:	**Started:**	15/04/2005		**Stopped:**	18/04/2005 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 209153 **Seq:** 1
Reported: 27/06/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 59
DOB: 16/04/1946
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia		The patient experienced tachycardia 110/m as confirmed on ECG.while on 30mg	Decreased Remeron dosage from 30mg to 15mg.

Medicine Details:

REMERON (Suspected) **Reason:**

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 209154 **Seq:** 1 **Gender:** F
Reported: 27/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 20/05/2005 **DOB:** 28/03/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed Serotonin syndrome Agitation Insomnia Nausea Restlessness Sedation		20/05/2005 dosage was increased to 30mg The patient developed suspected serotonin syndrome after Remeron was initiated with SSRI	

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 20/05/2005 0

FLUVOXAMINE MALEATE (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 209261 **Seq:** 1 **Gender:** M
Reported: 29/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 30Y
Onset Date: 05/01/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Tonic-clonic seizure due to suspected tramadol overdose with mirtazepine 60mg o nocte. Patient reports long-term use of both	Tramadol withdrawn,commenced on valproate

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 05/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 209356 **Seq:** 1 **Gender:** F
Reported: 01/07/2005 **Weight:** 100.00
Hospitalisation: Required a visit to the doctor **Age:** 49
Onset Date: 11/06/2005 **DOB:** 28/02/1956
Outcome: Recovered 15/06/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sedation Anger Irritability		The patient experienced prolonged sedation and irritability, increasing over the days to severe anger and rage, culminating in conflict	

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 209438 **Seq:** 1 **Gender:** M
Reported: 04/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 27
Onset Date: 21/06/2005 **DOB:** 01/09/1977
Outcome: Death, maybe drug 21/06/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	The patient experience an acute myocardial infarction and died whilst on	

Medicine Details:

CLOPINE (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 10/12/2004 **Stopped:** 21/06/2005

MIRTAZAPINE (Suspected) **Reason:** Depression
45.0 Milligram Daily Oral
Batch: **Started:** 15/01/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 209518 **Seq:** 1
Reported: 06/07/2005
Hospitalisation: Admitted to hospital
Onset Date: 15/10/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 47Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation	The patient commenced Avanza. On the first day she felt dizzy, had vertigo - had balance problems and couldn't head sideways, and she became very anxious. When Avanza was ceased she developed withdrawal symptoms over a two week period - agitation.	Avanza ceased.
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

INDERAL (Other drug) **Reason:** Migraine
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SEREPAX (Other drug) **Reason:** Anxiety neurosis
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 15/10/2003 **Stopped:** 15/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 209518 **Seq:** 1
Reported: 06/07/2005
Hospitalisation: Admitted to hospital
Onset Date: 15/10/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 47Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		
Vertigo	Caused or prolonged inpatient hospitalisation		

Medicine Details:

INDERAL (Other drug) **Reason:** Migraine
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SEREPAX (Other drug) **Reason:** Anxiety neurosis
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 15/10/2003 **Stopped:** 15/04/2004

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 209868 **Seq:** 1 **Gender:** M
Reported: 18/07/2005 **Weight:** 75.00
Hospitalisation: **Age:** 99Y
Onset Date: 30/06/2005 **DOB:**
Outcome: Death, maybe drug 07/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Sepsis	Death Death	The patient developed profound neutropenia, with a neutrophil count of 0.0, associated with sepsis.	G-CSF.

Medicine Details:

ASPIRIN (Other drug) **Reason:**
150.0 Milligram
Batch: **Started:** **Stopped:**

OXYCODONE HYDROCHLORIDE (Other drug) **Reason:** Pain
120.0 Milligram
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 20/05/2005 **Stopped:** 30/06/2005

PREDNISONE (Suspected) **Reason:**
Tablet 12.5 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/07/2005	Neutrophils				Neutrophil count is 0.0.

Additional Information:

Patient died of pneumonia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 210166 **Seq:** 1
Reported: 27/07/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 25/05/2005
Outcome: Recovered

Gender: F
Weight: 70.00
Age: 25Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Abdominal distension Feeling abnormal		The patient experienced extreme tiredness, bloating and had a spaced out feeling.	

Medicine Details:

AVANZA (Suspected) **Reason:**

Tablet 120.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 210180 **Seq:** 1 **Gender:** M
Reported: 27/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis	Caused or prolonged inpatient hospitalisation	Patient diagnosed with rhabdomyolysis and hepatitis. Patient presented to the emergency department 16 hours after taking 1.8g Remeron and 2 litres of wine.	Given IV fluids.
Hepatitis	Caused or prolonged inpatient hospitalisation		
Overdose	Caused or prolonged inpatient hospitalisation		

Medicine Details:

REMERON (Suspected) **Reason:** Depression
Tablet 1.8 Gram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of cognitive impairment secondary to carbon monoxide poisoning and depression. Source: Aust NZJ Psychiatry 2005;39(4):312-3.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 210330 **Seq:** 1 **Gender:** M
Reported: 02/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 45Y
Onset Date: 07/02/2005 **DOB:**
Outcome: Recovered 09/02/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures.	

Medicine Details:

SPIRONOLACTONE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

THIAMINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANTOPRAZOLE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LACTULOSE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Seizures secondary to Mirtazapine in setting of: chronic liver disease, GI bleed and known alcohol w/drawals.

Report Detail

Case Number: 210330 **Seq:** 1 **Gender:** M
Reported: 02/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 45Y
Onset Date: 07/02/2005 **DOB:**
Outcome: Recovered 09/02/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Tablet	30.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 08/02/2005

Laboratory Investigations:

Additional Information:

Seizures secondary to Mirtazapine in setting of: chronic liver disease, GI bleed and known alcohol w/drawals.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 210332 **Seq:** 1 **Gender:** M
Reported: 02/08/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 30/06/2005 **DOB:** 09/05/1966
Outcome: Recovered 04/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis Autoimmune hepatitis		Patient developed drug-induced hepatitis.	Ceased Mirtazapine, Olanzapine, Valproate, Carbamazepine, Cephalexin. Monitor ultrasound

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Batch: **Started:** 22/06/2005 **Stopped:** 28/06/2005 0

OLANZAPINE (Suspected) **Reason:** Depression
Batch: **Started:** 22/06/2005 **Stopped:** 28/06/2005 0

SODIUM VALPROATE (Suspected) **Reason:** Depression
Batch: **Started:** 22/06/2005 **Stopped:** 28/06/2005 0

CARBAMAZEPINE (Suspected) **Reason:** Depression
Batch: **Started:** 22/06/2005 **Stopped:** 28/06/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 210332 **Seq:** 1
Reported: 02/08/2005
Hospitalisation: Admitted to hospital
Onset Date: 30/06/2005
Outcome: Recovered 04/07/2005

Gender: M
Weight: 0.00
Age: 39
DOB: 09/05/1966
Causality: Causality possible

Reaction Detail

Medicine Details:

CEPHALEXIN (Suspected) **Reason:** Other prophylactic procedures

Batch: **Started:** 13/06/2005 **Stopped:** 29/06/2005 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 210659 **Seq:** 1 **Gender:** F
Reported: 12/08/2005 **Weight:** 55.00
Hospitalisation: Required a visit to the doctor **Age:** 17
Onset Date: 27/07/2005 **DOB:** 12/03/1988
Outcome: Recovered 29/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Amnesia Malaise Serotonin syndrome Somnolence Vomiting		The patient experienced suspected Serotonin Syndrome - dizziness, somnolence, vomiting, general malaise and amnesia	Bedrest and fluids.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 26/07/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 210897 **Seq:** 1 **Gender:** M
Reported: 18/08/2005 **Weight:** 105.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 10/08/2005 **DOB:** 16/06/1971
Outcome: Recovered 11/08/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	The patient experienced a grand mal fit after the second dose of Mirtazon. He felt strange after the first dose.	
Feeling abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Mirtazon (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 08/08/2005 **Stopped:** 10/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 211362 **Seq:** 1
Reported: 05/09/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 08/06/2005
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 41
DOB: 09/10/1963
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed Bursitis Pain		Mirtazapine 15mg/daily started on 05/05/05 for depression increased to 30mg/daily on 06/06/05. Patient noticed sudden onset over 2 to 3 days of pain in both shoulders and limited movement of joints.	Ultra sound confirmed bilat bursitis of shoulder capsule. Mirtazapine ceased.

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** 15/08/2004 S TERM **Stopped:**

Risperdal Consta (Other drug) **Reason:** Unspecified schizophrenia
Injection 25.0 Milligram Alternate weeks
Batch: **Started:** 03/08/2004 S TERM **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 06/06/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/09/2005	Other data				Ultrasound confirms bilateral bursitis of shoulder capsule.

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 211475 **Seq:** 1 **Gender:** M
Reported: 07/09/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Pancytopenia		The patient experienced a seizure after taking 2 to 3 doses of Remeron. He developed pancytopenia after 6 doses.	

Medicine Details:

PHENYTOIN SODIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CLONAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CARBAMAZEPINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Brain injury and alcohol abuse.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 211475 **Seq:** 1 **Gender:** M
Reported: 07/09/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

History: Brain injury and alcohol abuse.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 211489 **Seq:** 1
Reported: 07/09/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: M
Weight: 70.00
Age: 80
DOB: 05/11/1924
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms Tremor		The patient developed painful muscle spasms and tremor after reintroducing Mirtazapine, with the orofacial area particularly affected	Mirtazapine ceased.

Medicine Details:

PRAZOSIN HYDROCHLORIDE (Other drug)		**Reason:**	Essential benign hypertension
Batch:	**Started:**		**Stopped:**
DBL Aspirin (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
MADOPAR (Other drug)		**Reason:**	Paralysis agitans
Batch:	**Started:**		**Stopped:**
OMEGA-3 MARINE TRIGLYCERIDES (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug positive rechallenge. Patient has a history of Parkinson's disease, dementia and alcohol abuse.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 211489 **Seq:** 1
Reported: 07/09/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: M
Weight: 70.00
Age: 80
DOB: 05/11/1924
Causality: Causality certain

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 15/07/2005 S TERM **Stopped:**

Laboratory Investigations:

Additional Information:

Suspected drug positive rechallenge. Patient has a history of Parkinson's disease, dementia and alcohol abuse.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 211589 **Seq:** 1
Reported: 12/09/2005
Hospitalisation:
Onset Date: 27/08/2005
Outcome: Not yet recovered

Gender: F
Weight: 45.00
Age: 78
DOB: 16/11/1926
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient developed severe hyponatraemia.	IV N Saline given and cessation of drugs.

Medicine Details:

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
40.0 Milligram
Batch: **Started:** 10/08/2005 **Stopped:** 24/08/2005

PARACETAMOL (Other drug) **Reason:**
1.0 Gram
Batch: **Started:** **Stopped:**

HYDROCHLOROTHIAZIDE (Suspected) **Reason:** Essential benign hypertension
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 18/08/2005 **Stopped:** 27/08/2005

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 25/08/2005 **Stopped:** 29/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 211708 **Seq:** 1 **Gender:** F
Reported: 15/09/2005 **Weight:** 0.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia Arthralgia		Arthralgia and Myalgia	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Tablet 30.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 211741 **Seq:** 1
Reported: 19/09/2005
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2005
Outcome: Recovered

Gender: F
Weight: 57.00
Age: 28
DOB: 02/04/1977
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	The patient experienced a grand mal	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 06/07/2005 **Stopped:** 07/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212120 **Seq:** 1
Reported: 04/10/2005
Hospitalisation:
Onset Date: 13/09/2005
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 63
DOB: 05/09/1942
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare Aggression Agitation Nausea		The patient experienced nightmares, aggressive thoughts and behaviour out of keeping with usual, agitation and argumentative, was off balance and experienced nausea.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Neuroses

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 11/08/2005 **Stopped:** 20/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212284 **Seq:** 1 **Gender:** F
Reported: 06/10/2005 **Weight:** 52.00
Hospitalisation: Required a visit to the doctor **Age:** 52
Onset Date: 13/09/2005 **DOB:** 30/07/1953
Outcome: Recovered 15/09/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare Hallucination		Patient experienced nightmares and	Stopped Avanza

Medicine Details:

FISH OIL NOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

MICROGYNON (Other drug) **Reason:** Menopausal symptoms
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

STILNOX (Other drug) **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 30/08/2005 **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212300 **Seq:** 1 **Gender:** M
Reported: 07/10/2005 **Weight:** 72.00
Hospitalisation: **Age:** 39Y
Onset Date: 24/09/2005 **DOB:**
Outcome: Recovered 24/09/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Panic attack Chest discomfort Hyperhidrosis Sinus tachycardia Tremor		Patient experienced panic attack, sweating, sinus tachycardia, tembling and chest tightness	Ceased Avanza.

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212392 **Seq:** 1
Reported: 11/10/2005
Hospitalisation: Admitted to hospital
Onset Date: 06/01/2005
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 67
DOB: 24/04/1937
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation	The patient experienced dizziness.	Medication ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212434 **Seq:** 1 **Gender:** F
Reported: 12/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 19/09/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient experienced a seizure whilst taking Edronax.	

Medicine Details:

EDRONAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

EPILIM (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had a fit 10 years prior to reporting; has been controlled until 19 September 2005. Also taking antihypertensives.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212436 **Seq:** 1
Reported: 12/10/2005
Hospitalisation:
Onset Date: 29/09/2005
Outcome: Not yet recovered

Gender: F
Weight: 66.50
Age: 42
DOB: 06/10/1962
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema		The patient experienced facial puffiness.	Mirtazapine ceased.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 20/09/2005 **Stopped:** 21/10/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had Mirtazapine in April 2003 with no ill effect.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212654 **Seq:** 1
Reported: 18/10/2005
Hospitalisation: Admitted to hospital
Onset Date: 05/10/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 77
DOB: 18/10/1927
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation	The patient developed a widespread, erythematous, pinpoint to macular eruption rash, which was mildly itchy.	Sigmacort ointment and Betamethasone ointment.
Pruritus	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TIMOLOL MALEATE (Other drug) **Reason:** Unspecified glaucoma
Batch: **Started:** **Stopped:** 0

XALATAN (Other drug) **Reason:** Unspecified glaucoma
Batch: **Started:** **Stopped:**

BRIMONIDINE TARTRATE (Other drug) **Reason:** Unspecified glaucoma
Batch: **Started:** **Stopped:**

PROPINE (Other drug) **Reason:** Unspecified glaucoma
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Atorvastatin, Ramipril, Omeprazole, CaCO3, Ferrous Sulphate, Aspirin, Risendronate, Temazepam, Na Heparin and NaCL.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212654 **Seq:** 1
Reported: 18/10/2005
Hospitalisation: Admitted to hospital
Onset Date: 05/10/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 77
DOB: 18/10/1927
Causality: Causality possible

Reaction Detail

Medicine Details:

FLAREX (Other drug)			**Reason:**	Unspecified glaucoma
Batch:	**Started:**			**Stopped:**
ACETAZOLAMIDE (Other drug)			**Reason:**	Unspecified glaucoma
Batch:	**Started:**			**Stopped:**
CARBAMAZEPINE (Suspected)			**Reason:**	
	400.0 Milligram	Daily		Oral
Batch:	**Started:** 05/09/2005			**Stopped:**
MIRTAZAPINE (Suspected)			**Reason:**	Depression
Tablet	30.0 Milligram	Daily		Oral
Batch:	**Started:** 19/09/2005			**Stopped:**

Laboratory Investigations:

Additional Information:

Patient also taking Atorvastatin, Ramipril, Omeprazole, CaCO3, Ferrous Sulphate, Aspirin, Risendronate, Temazepam, Na Heparin and NaCL.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212667 **Seq:** 1
Reported: 18/10/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered with sequelae

Gender: M
Weight: 0.00
Age: 34
DOB: 13/03/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Agitation Drug therapy changed		The patient experienced aggravated depression, was agitated and irritable when he changed his therapy from Avanza to Axit	Axit ceased, changed back to [illegible]

Medicine Details:

Axit (Suspected) **Reason:** Depression

Tablet 0.5 Dose Unspecified Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212718 **Seq:** 1
Reported: 19/10/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 57
DOB: 19/11/1947
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Conjunctivitis		1. chronic conjunctivitis started soon after Avanza commenced in feb 2005. symptoms increased after increase in dose to 45mg daily late in April. settled as drug withdrawn recently. fairly clear time association with use of Avanza	WITHDRAWAL OF DRUG
Hepatic function abnormal		2. lethargy, recurrent sore throat and abnormal hepatic enzymes from early august 2005. also settling with drug withdrawal but less clearly associated with drug - may have been viral	WITHDRAWAL OF DRUG
Lethargy			
Pharyngolaryngeal pain			

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Capsule 30.0 Milligram Daily Oral

Batch: UNKNOWN **Started:** 22/02/2005 **Stopped:** 30/09/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/10/2005	Biochemistry				ALP 135, AST 62, ALT 104, GGT 79

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212818 **Seq:** 1 **Gender:** F
Reported: 25/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 84Y
Onset Date: 01/07/2005 **DOB:**
Outcome: Death, maybe drug 11/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypothermia	Death	The patient presented with hypothermia and altered conscious state. She experienced respiratory failure, was agitated and hypotensive. Principal diagnosis upon death was sepsis and respiratory failure.	Intubated, given Aciclovir, Penicillin, Vancomycin, Ceftriaxone, lumbar puncture.
Acidosis	Death		
Agitation	Death		
Altered state of consciousness	Death		
Hypotension	Death		
Respiratory failure	Death		
Sepsis	Death		

Medicine Details:

TERBINAFINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

GLICLAZIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

MINAX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

OSTELIN 1000 (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 212818 **Seq:** 1 **Gender:** F
Reported: 25/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 84Y
Onset Date: 01/07/2005 **DOB:**
Outcome: Death, maybe drug 11/07/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

ASPIRIN (Other drug)			**Reason:**			
Batch:	**Started:**			**Stopped:**		
AVANZA (Suspected)			**Reason:**			
Tablet	15.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**	04/07/2005	0
NEO-MERCAZOLE (Suspected)			**Reason:**			
Tablet	5.0	Milligram	Daily		Oral	
Batch:	**Started:**	23/07/2004		**Stopped:**		0

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 212838 **Seq:** 1
Reported: 26/10/2005
Hospitalisation:
Onset Date:
Outcome: Death, maybe drug

Gender: F
Weight: 0.00
Age: 51Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Death	Death	The patient had been receiving Lyrica for eight to nine days and the dose was being titrated up. She was found dead in her house. The cause is unknown and awaiting an autopsy.	
Aneurysm	Death		

Medicine Details:

Lyrica (Suspected) **Reason:** Pain

Capsule 225.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 0

AVANZA (Suspected) **Reason:** Depression

Tablet 0.5 Milligram Daily Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 212909 **Seq:** 1 **Gender:** U
Reported: 27/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		The patient experienced suspected neuroleptic malignant syndrome.	

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 213162 **Seq:** 1
Reported: 07/11/2005
Hospitalisation:
Onset Date: 23/03/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 87
DOB: 21/11/1917
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced abnormal liver function	Discontinuation of Amiodarone.

Medicine Details:

COLOXYL WITH SENNA (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
URAL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
FLORINEF (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
PANADEINE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/11/2005	ALT = SGPT	(less than 45)	01/03/2005	13	
07/11/2005	ALT = SGPT	(less than 45)	22/03/2005	47	
07/11/2005	ALT = SGPT	(less than 45)	30/03/2005	95	
07/11/2005	ALT = SGPT	(less than 45)	24/04/2005	25	
07/11/2005	AST = SGOT	(less than 40)	01/03/2005	20	
07/11/2005	AST = SGOT	(less than 40)	22/03/2005	57	
07/11/2005	AST = SGOT	(less than 40)	30/03/2005	30	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 213162 **Seq:** 1
Reported: 07/11/2005
Hospitalisation:
Onset Date: 23/03/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 87
DOB: 21/11/1917
Causality: Causality possible

Reaction Detail

Medicine Details:

HEPARIN SODIUM (Other drug)			**Reason:**	
Batch:	**Started:**			**Stopped:**
AVANZA (Suspected)			**Reason:**	
Tablet	60.0 Milligram			Oral
Batch:	**Started:** 23/03/2005			**Stopped:**
DILTAHEXAL (Suspected)			**Reason:**	
				Oral
Batch:	**Started:**			**Stopped:**
CORDARONE X (Suspected)			**Reason:**	Otr&nos disord of heart rhythm
Tablet	100.0 Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/11/2005	AST = SGOT	(less than 40)	24/04/2005	27	
07/11/2005	Albumin	(33-47)	01/03/2005	37	
07/11/2005	Albumin	(33-47)	22/03/2005	32	
07/11/2005	Albumin	(33-47)	30/03/2005	28	
07/11/2005	Albumin	(33-47)	24/04/2005	35	
07/11/2005	Bilirubin	(less than 20)	01/03/2005	15	
07/11/2005	Bilirubin	(less than 20)	22/03/2005	25	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 213162 **Seq:** 1
Reported: 07/11/2005
Hospitalisation:
Onset Date: 23/03/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 87
DOB: 21/11/1917
Causality: Causality possible

Reaction Detail

Medicine Details:

EFEXOR (Suspected)			**Reason:**	Depression	
Tablet	150.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
PRAVACHOL (Suspected)			**Reason:**	Othr&unspec metabolic diseases	
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/11/2005	Bilirubin	(less than 20)	24/04/2005	8	
07/11/2005	Bilirubin	(less than 20)	30/03/2005	20	
07/11/2005	GGT = SGGT =	(less than 50)	01/03/2005	83	
07/11/2005	GGT = SGGT =	(less than 50)	24/04/2005	156	
07/11/2005	GGT = SGGT =	(less than 50)	30/03/2005	85	
07/11/2005	GGT = SGGT =	(less than 50)	22/03/2005	92	
07/11/2005	Haemoglobin	(24-45)	01/03/2005	33	

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 213162 **Seq:** 1
Reported: 07/11/2005
Hospitalisation:
Onset Date: 23/03/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 87
DOB: 21/11/1917
Causality: Causality possible

Reaction Detail

Medicine Details:

COLOXYL WITH SENNA (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
URAL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
FLORINEF (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
PANADEINE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/11/2005	Haemoglobin	(24-45)	22/03/2005	30	
07/11/2005	Haemoglobin	(24-45)	24/04/2005	33	
07/11/2005	Haemoglobin	(24-45)	30/03/2005	29	
07/11/2005	Lactate	(110-250)	01/03/2005	395	
07/11/2005	Lactate	(110-250)	22/03/2005	316	
07/11/2005	Lactate	(110-250)	24/04/2005	270	
07/11/2005	Lactate	(110-250)	30/03/2005	321	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 213162 **Seq:** 1
Reported: 07/11/2005
Hospitalisation:
Onset Date: 23/03/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 87
DOB: 21/11/1917
Causality: Causality possible

Reaction Detail

Medicine Details:

HEPARIN SODIUM (Other drug)			**Reason:**	
Batch:	**Started:**			**Stopped:**
AVANZA (Suspected)			**Reason:**	
Tablet	60.0 Milligram			Oral
Batch:	**Started:** 23/03/2005			**Stopped:**
DILTAHEXAL (Suspected)			**Reason:**	
				Oral
Batch:	**Started:**			**Stopped:**
CORDARONE X (Suspected)			**Reason:**	Otr&nos disord of heart rhythm
Tablet	100.0 Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/11/2005	Other data	(40-100)	01/03/2005	143	Alk Phosphatase
07/11/2005	Other data	(40-100)	22/03/2005	187	Alk Phosphatase
07/11/2005	Other data	(40-100)	30/03/2005	161	Alk Phosphatase
07/11/2005	Other data	(40-100)	24/04/2005	250	Alk Phosphatase

Additional Information:

Report Detail

Case Number: 213162 **Seq:** 1
Reported: 07/11/2005
Hospitalisation:
Onset Date: 23/03/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 87
DOB: 21/11/1917
Causality: Causality possible

Reaction Detail

Medicine Details:

EFEXOR (Suspected)			**Reason:**	Depression	
Tablet	150.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
PRAVACHOL (Suspected)			**Reason:**	Othr&unspec metabolic diseases	
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 213327 **Seq:** 1 **Gender:** F
Reported: 10/11/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 81
Onset Date: **DOB:** 02/08/1924
Outcome: Recovered 29/09/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Patient experienced urinary incontinence.	

Medicine Details:

OXYCONTIN (Other drug) **Reason:** Pain
Batch: **Started:** **Stopped:** 0

CLOPIDOGREL (Other drug) **Reason:** Other coagulation defects
Batch: **Started:** **Stopped:**

AMLODIPINE (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

GLYCERYL TRINITRATE (Other drug) **Reason:** Angina pectoris w hypertension
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 213327 **Seq:** 1
Reported: 10/11/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered 29/09/2005

Gender: F
Weight: 0.00
Age: 81
DOB: 02/08/1924
Causality: Causality probable

Reaction Detail

Medicine Details:

OXYBUTYNIN HYDROCHLORIDE (Other drug)			**Reason:** Incontinence of urine	
Batch:	**Started:**			**Stopped:**
MIRTAZAPINE (Suspected)			**Reason:** Depression	
Tablet	30.0 Milligram	Daily		Oral
Batch:	**Started:** 07/09/2005			**Stopped:** 27/09/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 213870 **Seq:** 1 **Gender:** F
Reported: 29/11/2005 **Weight:** 57.00
Hospitalisation: Required a visit to the doctor **Age:** 49
Onset Date: 01/11/2005 **DOB:** 23/10/1956
Outcome: Recovered 17/11/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		The patient experienced arthralgia of the feet, ankles and knees.	Mirtazapine ceased.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 19/09/2005 **Stopped:** 10/11/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214374 **Seq:** 1 **Gender:** F
Reported: 16/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 13Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		The patient was noted to have significant pedal oedema of the legs.	

Medicine Details:

OLANZAPINE (Other drug) **Reason:** Anorexia
Batch: **Started:** **Stopped:** 0

PHOSPHATE SOLUTION (Other drug) **Reason:**
Batch: **Started:** **Stopped:** 0

OLANZAPINE (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 18/05/2005 **Stopped:**

PHOSPHATE-SANDOZ (Other drug) **Reason:**
Tablet 1.5 Gram Daily Oral
Batch: **Started:** 18/11/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214374 **Seq:** 1
Reported: 16/12/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 13Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Anorexia

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 15/04/2005 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214525 **Seq:** 1
Reported: 03/01/2006
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 36
DOB: 04/09/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		The patient experienced suicidal thinking.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214533 **Seq:** 1 **Gender:** F
Reported: 03/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 09/07/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania Insomnia		The patient has gained five kg in weight on Avanza since about mid 2004. Her sleep is not good - she is up every couple of hours	

Medicine Details:

BACLOFEN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

QUININE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

XANAX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 214533 **Seq:** 1
Reported: 03/01/2006
Hospitalisation:
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 50
DOB: 09/07/1955
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected)		**Reason:**	
Tablet			Oral
Batch:	**Started:**	**Stopped:**	
TRAMAL (Suspected)		**Reason:**	
Batch:	**Started:**	**Stopped:**	

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 214538 **Seq:** 1 **Gender:** M
Reported: 03/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 58
Onset Date: **DOB:** 03/04/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Akathisia Restlessness		The patient experienced restlessness. He got very nervous when he had to sit in a chair and was always pacing up and down. He also had difficulty sleeping.	

Medicine Details:

TRAMAL SR (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of various medications.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214555 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 10/09/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Aggression Suicidal ideation		Whilst on Avanza, which had not been prescribed, the patient became suicidal and violent	Avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214557 is the second sequence to this report and report 214558 is the third sequence.

Report Detail

Case Number: 214561 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Delirium		The patient experienced akathisia and delirium. He suffered depression and agitation and wakes after sleeping only three hours, sleeping no more after that.	

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

RISPERIDONE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214562 **Seq:** 1 **Gender:** F
Reported: 04/01/2006 **Weight:** 90.00
Hospitalisation: Required a visit to the doctor **Age:** 58
Onset Date: 23/10/2005 **DOB:** 16/01/1947
Outcome: Recovered 06/11/2005 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anger Aggression Irritability Paranoia		Patient commenced Avanza which she continued for 2 weeks, during which time she felt angrey, irritable, aggressive and on the verge of violence, on several occasions appeared paranoid to others.	

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 22/10/2005 **Stopped:** 04/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug certain rechallenge.
History: Previous exposure to Avanza 15mg nocte 1/12/04 for few days - similar symptoms.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214569 **Seq:** 1 **Gender:** F
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 27/07/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania Mood swings Restless legs syndrome Suicidal ideation			

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214703 **Seq:** 1 **Gender:** M
Reported: 09/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 15/03/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sperm count decreased	Incapacity/disability	Patient has a very low sperm count.	

Medicine Details:

EPILIM (Suspected) **Reason:** Unspecifid affective psychosis
Tablet Oral
Batch: **Started:** 15/08/2000 **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 900.0 Milligram Daily Oral
Batch: **Started:** 15/10/2001 **Stopped:**

LUVOX (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 15/05/2000 **Stopped:** 15/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214734 **Seq:** 1 **Gender:** M
Reported: 09/01/2006 **Weight:** 70.00
Hospitalisation: **Age:** 34
Onset Date: 15/11/2005 **DOB:** 13/09/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anaphylactoid reaction	Life [illegible]	The patient experienced suspected anaphylactoid reaction.	

Medicine Details:

METHADONE HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

FLUNITRAZEPAM (Suspected) **Reason:** Specific disorders of sleep
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 214881 **Seq:** 1 **Gender:** M
Reported: 11/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: 15/07/2005 **DOB:** 31/07/1970
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia		Patient experienced alopecia.	Ceased Avanza.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 20/04/2005 **Stopped:** 26/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215318 **Seq:** 1
Reported: 27/01/2006
Hospitalisation:
Onset Date:
Outcome: Unknown

Gender: M
Weight: 80.00
Age: 26
DOB: 11/05/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Depression Irritability Palpitations		The patient felt drowsy, would cry at the drop of a hat and suffered anxiety and depression. He was "walking around like a zombie in a daze all the time", had panic attacks, was unable to sleep, was vomiting, had difficulty eating, lost weight, had palpitations, had pain in his left arm "like a heart attack", became irritable, had surges of anger and rage, had suicidal thoughts and tingling in his right foot.	Vioxx ceased.

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

VIOXX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215318 **Seq:** 1 **Gender:** M
Reported: 27/01/2006 **Weight:** 80.00
Hospitalisation: **Age:** 26
Onset Date: **DOB:** 11/05/1979
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Panic attack Somnolence Vomiting			

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

VIOXX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215325 **Seq:** 1 **Gender:** M
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 05/01/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Libido decreased Serotonin syndrome		The patient experienced impulses to suicide and a total sexual loss of libido.	

Medicine Details:

VIOXX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215336 **Seq:** 1 **Gender:** M
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 26/04/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Depression Homicidal ideation Insomnia Paranoia Suicide attempt		The patient was jittery and suffering from akathisia. He experienced increasing agitation, paranoid thoughts, wanted to kill inmates and had swallowed razor blades. He had slashed his wrists and was depressed with violent thoughts, couldn't sleep, had voice hallucinations, restless legs, paced, could not sit, his face itched	

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

METHADONE HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

HEROIN (Suspected) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:**

Amphetamine (Suspected) **Reason:**
3.0 Gram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215347 **Seq:** 1 **Gender:** M
Reported: 30/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Drug withdrawal syndrome Mania Serotonin syndrome Suicidal ideation		The patient experienced akathisia. He was restless and could not sit. He suffered withdrawal syndrome, including suicidality and manic switch. He developed suspected serotonin syndrome.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215498 **Seq:** 1
Reported: 02/02/2006
Hospitalisation:
Onset Date: 18/01/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 45Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancytopenia	Caused or prolonged inpatient hospitalisation	Patient developed pancytopaenia sysptoms of lethargy, malaise, fatigue.	Transfusion 2 untis RC.
Fatigue	Caused or prolonged inpatient hospitalisation		
Lethargy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

COMBIVIR (Other drug) **Reason:** Hiv infection
Batch: **Started:** **Stopped:** 0

NEVIRAPINE (Other drug) **Reason:** Hiv infection
Batch: **Started:** **Stopped:**

VALTREX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/02/2006	Haemoglobin		05/01/2006	139	
02/02/2006	Haemoglobin		18/01/2006	100	
02/02/2006	Haemoglobin		24/01/2006	80	
02/02/2006	Platelets		05/01/2006	210	
02/02/2006	Platelets		18/01/2006	193	
02/02/2006	Platelets		24/01/2006	122	
02/02/2006	White blood cells		05/01/2006	3.78	

Additional Information:

HIV positive, Hep C positive, no previous exposure to either drug. On 24 January 2006 his lab values were still decreasing

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215498 **Seq:** 1
Reported: 02/02/2006
Hospitalisation:
Onset Date: 18/01/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 45Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

SODIUM VALPROATE (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/02/2006	White blood cells		18/01/2006	3.18	
02/02/2006	White blood cells		24/01/2006	2.4	

Additional Information:

HIV positive, Hep C positive, no previous exposure to either drug. On 24 January 2006 his lab values were still decreasing

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215500 **Seq:** 1
Reported: 02/02/2006
Hospitalisation:
Onset Date: 27/12/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 63
DOB: 28/08/1942
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Agitation Dyskinesia Headache Hyperreflexia Hypertonia		Patient developed serotonin syndrome, increased agitation, headache, hyperreflexia, variable hypertonia, rhythemic movements of eyelids and eyebrows.	Withdrawal of Gabapentin, Stilnox, Promethazine.

Medicine Details:

MIRTAZAPINE (Suspected)		**Reason:** Depression	
Batch:	**Started:**		**Stopped:**
GABAPENTIN (Suspected)		**Reason:** Pain	
Batch:	**Started:** 23/12/2005		**Stopped:** 16/01/2006
STILNOX (Suspected)		**Reason:**	
Batch:	**Started:**		**Stopped:** 16/01/2006
ROXITHROMYCIN (Suspected)		**Reason:** Chronic sinusitis	
Batch:	**Started:**		**Stopped:** 15/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Time course corresponds best with Gabapentin, only medication that was new to her.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215500 **Seq:** 1
Reported: 02/02/2006
Hospitalisation:
Onset Date: 27/12/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 63
DOB: 28/08/1942
Causality: Causality possible

Reaction Detail

Medicine Details:

PROMETHAZINE HYDROCHLORIDE (Suspected) **Reason:** Other puritis conditions
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 16/01/2006

Laboratory Investigations:

Additional Information:

Time course corresponds best with Gabapentin, only medication that was new to her.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215509 **Seq:** 1
Reported: 02/02/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 84
DOB: 10/02/1921
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vasculitis	Life	Patient experienced renal failure, polymyalgia, polyarthralgia, petechial rash in lower legs, C.Reactive protein increased, Ferritin increased, ESR increased, nightmares/vivid dreams, tingling fingers andr toes, restless legs, fever, drowsiness, weight loss, dizziness, seizures, oedema, vasculitis. Other symptoms included vasculitis, heart cramps, muscle cramps, joint point, body heat with excessive sweating, swollen hands and feet, headache and hallucinations	
Angina pectoris	Life		
Arthralgia			
C-reactive protein increased			

Medicine Details:

AVANZA (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/02/2006	Antinuclear factor				ANA positive 1:40, speckled.
02/02/2006	Creatinine	3-5.1.			Cr - 25.
02/02/2006	Erythrocyte				ESR - 53.
02/02/2006	Ferritin				Ferritin - 1622.
02/02/2006	Other data				Uric Acid - 0.5.
02/02/2006	Skin biopsy				Skin biopsy - leucocytoclastic vasculitis.

Additional Information:

Asbestosis, HTN, PUD, Left mastectomy and CVA.

Report Detail

Case Number: 215509 **Seq:** 1
Reported: 02/02/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 84
DOB: 10/02/1921
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			
Dizziness			
Hallucination	Life		
Hyperhidrosis	Life		
Muscle spasms	Life		
Myalgia			
Nightmare			
Oedema			
Paraesthesia			
Petechiae			
Pyrexia			

Medicine Details:

AVANZA (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Asbestosis, HTN, PUD, Left mastectomy and CVA.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215509 **Seq:** 1
Reported: 02/02/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 84
DOB: 10/02/1921
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Red blood cell sedimentation rate Renal failure Restless legs syndrome Serum ferritin increased Somnolence Weight decreased	Life		

Medicine Details:

AVANZA (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Asbestosis, HTN, PUD, Left mastectomy and CVA.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215713 **Seq:** 1
Reported: 10/02/2006
Hospitalisation: Admitted to hospital
Onset Date: 05/01/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 06/09/1932
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Patient developed serotonin syndrome, motor restlessness and shivering.	Edronax, Avanza and Zoloft
Akathisia	Caused or prolonged inpatient hospitalisation		
Chills	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATENOLOL (Other drug) **Reason:**
Tablet 25.0 Milligram Oral
Batch: **Started:** **Stopped:**

SOMAC (Other drug) **Reason:**
40.0 Milligram
Batch: **Started:** **Stopped:**

COVERSYL (Other drug) **Reason:**
Tablet 8.0 Milligram Oral
Batch: **Started:** **Stopped:** 03/01/2006

COLOXYL (Other drug) **Reason:**
120.0 Milligram
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Endep recently ceased (prior to 28/12/05). Patient also has anorexia nervosa and SIADH.

Report Detail

Case Number: 215713 **Seq:** 1
Reported: 10/02/2006
Hospitalisation: Admitted to hospital
Onset Date: 05/01/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 06/09/1932
Causality: Causality possible

Reaction Detail

Medicine Details:

ZYPREXA (Other drug)			**Reason:**			
	10.0	Milligram	As necessary			
Batch:	**Started:**			**Stopped:**	01/01/2006	Ceased
ANTENEX (Suspected)			**Reason:**	Anxiety neurosis		
Tablet	10.0	Milligram	As necessary	Oral		
Batch:	**Started:**			**Stopped:**		0
ZOLOFT (Suspected)			**Reason:**	Anxiety neurosis		
Tablet	150.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**		
AVANZA (Suspected)			**Reason:**	Depression		
Tablet	30.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**		

Laboratory Investigations:

Additional Information:

Endep recently ceased (prior to 28/12/05). Patient also has anorexia nervosa and SIADH.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215713 **Seq:** 1
Reported: 10/02/2006
Hospitalisation: Admitted to hospital
Onset Date: 05/01/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 06/09/1932
Causality: Causality possible

Reaction Detail

Medicine Details:

EDRONAX (Suspected) **Reason:**

Tablet 4.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Endep recently ceased (prior to 28/12/05). Patient also has anorexia nervosa and SIADH.

Report Detail

Case Number: 215901 **Seq:** 1
Reported: 16/02/2006
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2005
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 73
DOB: 22/04/1931
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	? EPSE secondary to Risperidone. ? Neuroleptic malignant syndrome and oversedation with background of dementia.	Withdrawal of therapy.
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

COLOXYL WITH SENNA (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

PARACETAMOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

OMEPRAZOLE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

TRIMETHOPRIM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 215901 **Seq:** 1
Reported: 16/02/2006
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2005
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 73
DOB: 22/04/1931
Causality: Causality possible

Reaction Detail

Medicine Details:

DIPHENOXYLATE HYDROCHLORIDE (Suspected)			**Reason:**			
Tablet	2.5	Milligram	As necessary	Oral		
Batch:	**Started:**			**Stopped:**	04/03/2006	
MIRTAZAPINE (Suspected)			**Reason:**	Depression		
Tablet	30.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**	04/03/2005	
RISPERIDONE (Suspected)			**Reason:**			
Tablet	1.0	Milligram	Daily	Oral		
Batch:	**Started:**	15/07/2004		**Stopped:**	04/03/2005	0

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215912 **Seq:** 1
Reported: 16/02/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 08/02/2006
Outcome: Not yet recovered

Gender: M
Weight: 58.00
Age: 33
DOB: 15/05/1972
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		The patient experienced increased liver	Ceased Avanza.

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
5.0 Milligram
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 03/12/2005 **Stopped:** 10/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/02/2006	ALT = SGPT				ALT - 292.
16/02/2006	AST = SGOT				AST - 382.
16/02/2006	Bilirubin				Bili - 6.
16/02/2006	GGT = SGGT =				GGT - 550.
16/02/2006	SAP = ALP				ALP - 175.

Additional Information:

Known fatty liver; ultrasound liver 13/02/06 - fatty liver only. But liver enzymes not so elevated in past. No/minimal alchol. Hep B/C negative.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 215993 **Seq:** 1 **Gender:** M
Reported: 20/02/2006 **Weight:** 75.00
Hospitalisation: Admitted to hospital **Age:** 75
Onset Date: 09/02/2006 **DOB:** 08/01/1931
Outcome: Recovered 12/01/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon	Caused or prolonged inpatient hospitalisation	The patient experienced hyponatraemia with unsteadiness and some renal impairment	Ceased Avapro HCT and Mirtazapine, restrict water, given IV Saline
Balance disorder	Caused or prolonged inpatient hospitalisation		
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

BRICANYL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ASPIRIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

NEXIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

VOLTAREN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/02/2006	Creatinine				Creat - .192mmol/L.
20/02/2006	Serum osmolality				Osmol - 267.
20/02/2006	Sodium				Sodium - 120.
20/02/2006	Urine osmolality				Urine - 198.

Additional Information:

Report Detail

Case Number: 215993 **Seq:** 1 **Gender:** M
Reported: 20/02/2006 **Weight:** 75.00
Hospitalisation: Admitted to hospital **Age:** 75
Onset Date: 09/02/2006 **DOB:** 08/01/1931
Outcome: Recovered 12/01/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal impairment	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVAPRO HCT 150/12.5 (Suspected) **Reason:** Essential benign hypertension
Tablet Oral
Batch: **Started:** **Stopped:** 09/02/2006

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 09/02/2006

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216022 **Seq:** 1
Reported: 21/02/2006
Hospitalisation:
Onset Date: 22/08/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 34
DOB: 08/07/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Caused or prolonged inpatient hospitalisation	The patient experienced ankle oedema, which increased to groin level.	Remeron ceased, treated with

Medicine Details:

DIAZEPAM (Other drug) **Reason:** Anxiety neurosis
Batch: **Started:** **Stopped:**

METHADONE HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CITALOPRAM HYDROBROMIDE (Other drug) **Reason:** Depression
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216022 **Seq:** 1
Reported: 21/02/2006
Hospitalisation:
Onset Date: 22/08/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 34
DOB: 08/07/1971
Causality: Causality possible

Reaction Detail

Medicine Details:

PROPRANOLOL HYDROCHLORIDE (Other drug)		**Reason:**	Headache
Batch:	**Started:**	**Stopped:**	
REMERON (Suspected)		**Reason:**	Depression
Tablet			Oral
Batch:	**Started:** 28/07/2005	**Stopped:**	27/08/2005

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 216272 **Seq:** 1
Reported: 06/03/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 15/02/2006
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 37
DOB: 08/03/1968
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Myoclonus Restlessness		Patient experienced feelings of electrical impulses under skin, myoclonic jerking in arms and legs. Waking from sleep, restlessness during day, jerking starts after taking dose, lasts 2 and half hours.	

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:** Myxedema

Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 20/01/2006 **Stopped:** 20/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous episode of side effects on Mirtazapine.

Report Detail

Case Number: 216294 **Seq:** 1
Reported: 07/03/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 03/01/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 83
DOB: 14/02/1922
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Patient developed mild hyponatraemia.	

Medicine Details:

ASPIRIN (Other drug) **Reason:**
100.0 Milligram
Batch: **Started:** **Stopped:**

PROPRANOLOL HYDROCHLORIDE (Other drug) **Reason:**
20.0 Milligram
Batch: **Started:** 04/11/2005 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 30/01/2005 **Stopped:**

CARBIMAZOLE (Suspected) **Reason:**
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/03/2006	Sodium	(135-145)	06/01/2006	131	Baseline ~139

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216294 **Seq:** 1
Reported: 07/03/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 03/01/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 83
DOB: 14/02/1922
Causality: Causality possible

Reaction Detail

Medicine Details:

OMEPRAZOLE (Suspected)			**Reason:**	
Tablet	20.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216511 **Seq:** 1 **Gender:** F
Reported: 15/03/2006 **Weight:** 68.00
Hospitalisation: Required a visit to the doctor **Age:** 72
Onset Date: 25/01/2006 **DOB:** 11/10/1933
Outcome: Recovered 02/02/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Somnolence Therapy regimen changed		Patient experienced fine tremor and grogginess, therapy regimen changed (increase to 30mg on 24/01/2006).	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Anxiety neurosis
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 19/01/2006 **Stopped:** 31/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216558 **Seq:** 1
Reported: 16/03/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 25/02/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Agitation Anxiety		Patient experienced pins and needles, tingling right arm, increased feelings of fear, anxiety and agitation.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 23/02/2006 **Stopped:** 01/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216594 **Seq:** 1 **Gender:** M
Reported: 21/03/2006 **Weight:** 68.00
Hospitalisation: Required a visit to the doctor **Age:** 72
Onset Date: 10/11/2005 **DOB:** 03/03/1933
Outcome: Recovered 13/11/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed Oedema peripheral Sleep paralysis		Sleep paracysis, therapy regiment changed and also experienced swollen feet.	Stopped the larger dose of

Medicine Details:

AROPAX (Other drug) **Reason:**
40.0 Milligram
Batch: **Started:** 15/06/2004 **Stopped:**

XELODA (Other drug) **Reason:** Malig neo lg intest&colon nos
8.0 Milligram
Batch: **Started:** 15/08/2004 **Stopped:**

AVANZA (Other drug) **Reason:** Pain
15.0 Milligram
Batch: **Started:** 02/10/2005 **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 22/10/2005 **Stopped:** 11/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216782 **Seq:** 1
Reported: 29/03/2006
Hospitalisation: Admitted to hospital
Onset Date: 26/07/2005
Outcome: Recovered

Gender: F
Weight: 47.00
Age: 92
DOB: 29/07/1912
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient developed hyponatraemia.	Mirtazapine ceased.

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ISOSORBIDE DINITRATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ALENDRONATE SODIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

WARFARIN SODIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 216782 **Seq:** 1
Reported: 29/03/2006
Hospitalisation: Admitted to hospital
Onset Date: 26/07/2005
Outcome: Recovered

Gender: F
Weight: 47.00
Age: 92
DOB: 29/07/1912
Causality: Causality possible

Reaction Detail

Medicine Details:

RAMIPRIL (Other drug)			**Reason:**		
Batch:	**Started:**			**Stopped:**	
MIRTAZAPINE (Suspected)			**Reason:**		
Tablet	15.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	26/07/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216800 **Seq:** 1
Reported: 30/03/2006
Hospitalisation:
Onset Date: 14/02/2006
Outcome: Not yet recovered

Gender: M
Weight: 65.00
Age: 39Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis		Patient complained of myalgias which did not resolve over next 10 day.	Ceased Chlorpromazine and Mirtazapine.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Specific disorders of sleep

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 25/01/2006 **Stopped:** 24/02/2006 0

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 13/01/2006 **Stopped:** 24/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/03/2006	Creatine		23/02/2006	10300	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216929 **Seq:** 1 **Gender:** F
Reported: 03/04/2006 **Weight:** 0.00
Hospitalisation: **Age:** 76
Onset Date: 28/03/2006 **DOB:** 19/01/1930
Outcome: Recovered 29/03/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms		Patient took an Azanza tablet at approximately 9.00pm, about 30 minutes later the patient felt like her whole body was in spasm. This lasted about 6hrs before it resolved without intervention. She described it as a case of very severe restless leg syndrome all over the body	NIL- Patient swapped to anoter anti-depressant

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 27/03/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 216981 **Seq:** 1
Reported: 04/04/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 03/02/2006
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred Abnormal sensation in eye Myopia		Blurry vision; loss of long distance vision making reading signs etc difficult. Feeling of pressure in and around the right eye; radiating up the the temple.	Ceased medication.

Medicine Details:

Axit (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 31/01/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 217311 **Seq:** 1
Reported: 11/04/2006
Hospitalisation:
Onset Date: 17/03/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 48
DOB: 08/11/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation Hallucination, auditory Nausea		Patient experienced nausea, appetite loss, weight loss of 3kg and hearing voices in the head (saying things such as "go and get a gun")	

Medicine Details:

AVANZA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

CELAPRAM (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

EFEXOR-XR (Suspected) **Reason:** Depression
Capsule 37.5 Milligram Daily Oral
Batch: **Started:** 17/03/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient reported that hearing voices in her head was experienced with other antidepressants as well.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 217489 **Seq:** 1 **Gender:** M
Reported: 19/04/2006 **Weight:** 0.00
Hospitalisation: **Age:** 52
Onset Date: 27/03/2006 **DOB:** 06/11/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia		Leucopenia and Neutropenia.	Clopine ceased.

Medicine Details:

CLOPINE (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 16/02/2006 **Stopped:** 26/03/2006

MIRTAZAPINE (Suspected) **Reason:** Depression
45.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2006	Neutrophils		26/03/2006	0.5	
19/04/2006	Neutrophils		20/03/2006	3.3	
19/04/2006	Neutrophils		03/04/2006	2.2	
19/04/2006	Neutrophils		01/04/2006	1.8	
19/04/2006	White blood cells		26/03/2006	1.7	
19/04/2006	White blood cells		20/03/2006	4.4	
19/04/2006	White blood cells		01/04/2006	3.6	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 217489 **Seq:** 1
Reported: 19/04/2006
Hospitalisation:
Onset Date: 27/03/2006
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 52
DOB: 06/11/1953
Causality: Causality possible

Reaction Detail

Medicine Details:

CLOPINE (Suspected)			**Reason:**		
Tablet	400.0	Milligram	Daily		Oral
Batch:	**Started:**	16/02/2006		**Stopped:**	26/03/2006
MIRTAZAPINE (Suspected)			**Reason:**	Depression	
	45.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2006	White blood cells		03/04/2006	3.8	

Additional Information:

Report Detail

Case Number: 217701 **Seq:** 1
Reported: 26/04/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 13/04/2006
Outcome: Recovered with sequelae

Gender: F
Weight: 62.00
Age: 64
DOB: 06/11/1941
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anticonvulsant drug level decreas		Fall in Dilantin to subtherapeutic levels (24 mmol/l) after being in high therapeutic range for 2 years (48-83 mmol/l).	

Medicine Details:

AVANZA (Interaction) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 15/09/2005 **Stopped:**

DILANTIN (Interaction) **Reason:** Convulsions
330.0 Milligram Daily
Batch: **Started:** 15/06/2002 **Stopped:**

OROXINE (Other drug) **Reason:** Myxedema
200.0 Microgram
Batch: **Started:** 15/06/2002 **Stopped:** 0

PRAVACHOL (Other drug) **Reason:** Othr&unspec metabolic diseases
40.0 Milligram
Batch: **Started:** 15/06/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 217701 **Seq:** 1
Reported: 26/04/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 13/04/2006
Outcome: Recovered with sequelae

Gender: F
Weight: 62.00
Age: 64
DOB: 06/11/1941
Causality: Causality possible

Reaction Detail

Medicine Details:

HYSONE (Other drug) **Reason:**
34.0 Milligram
Batch: **Started:** 15/06/2002 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 217787 **Seq:** 1 **Gender:** M
Reported: 01/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Pollakiuria		Patient reported what seems a paradoxical reaction in which he became extra alert, couldn't sleep and had frequency of urine am	

Medicine Details:

AVANZA (Suspected) **Reason:** Irritable colon
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 217913 **Seq:** 1 **Gender:** M
Reported: 02/05/2006 **Weight:** 92.00
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 05/03/1953
Outcome: Recovered 20/04/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Confusional state Irritability Suicidal ideation		Patient was prescribed Avanza with Lexapro was added, suffered significant agitation, confusion, suicidal thoughts, irritability	Ceased Avanza.

Medicine Details:

NEURONTIN (Other drug) **Reason:**
900.0 Milligram
Batch: **Started:** L TERM **Stopped:**

LIPITOR (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ACCUPRIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Batch: **Started:** 15/03/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 217913 **Seq:** 1 **Gender:** M
Reported: 02/05/2006 **Weight:** 92.00
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 05/03/1953
Outcome: Recovered 20/04/2006 **Causality:** Causality possible

Reaction Detail

Medicine Details:

Lexapro (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 15/04/2004 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 217929 **Seq:** 1
Reported: 03/05/2006
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 71
DOB: 18/10/1934
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus generalised		Patient developed a generalised itch and feeling of fullness in the head.	Mirtazapine discontinued. Treated with Promethazine

Medicine Details:

CYCLOSPORIN-A (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
ASPIRIN (Other drug)		**Reason:**	Other coagulation defects
Batch:	**Started:**		**Stopped:** 0
CAPTOPRIL (Other drug)		**Reason:**	Essential benign hypertension
Batch:	**Started:**		**Stopped:**
PREDNISOLONE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 217929 **Seq:** 1
Reported: 03/05/2006
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 71
DOB: 18/10/1934
Causality: Causality possible

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Weekly Oral

Batch: **Started:** 30/01/2006 **Stopped:** 22/02/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 218053 **Seq:** 1 **Gender:** F
Reported: 05/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 79
Onset Date: 09/03/2006 **DOB:** 16/04/1926
Outcome: Recovered 15/03/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient developed hyponatraemia, nausea, lightheaded, abdominal pain, hypokalaemia	Ceased Indapamide, decreased Frusemide to 40mg mane, decreased Avanza to 15mg nocte, valproate levels (n), chlovrescent, fluid restriction 152/day (no plain water) replace iIndapamide with Spironolactone.
Abdominal pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SOMAC (Other drug) **Reason:** Peptic ulcer nos w/o ment perf
Batch: **Started:** **Stopped:**

EPILIM (Other drug) **Reason:** Other&unspecified epilepsy
Batch: **Started:** **Stopped:**

FOSAMAX ONCE WEEKLY TABLETS (Other drug) **Reason:** Other diseases of bone
Batch: **Started:** **Stopped:**

OSTELIN 1000 (Other drug) **Reason:** Other diseases of bone
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/05/2006	Potassium				K - 2.7.
05/05/2006	Sodium				Na - 124.

Additional Information:

Report Detail

Case Number: 218053 **Seq:** 1 **Gender:** F
Reported: 05/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 79
Onset Date: 09/03/2006 **DOB:** 16/04/1926
Outcome: Recovered 15/03/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation		
Hypokalaemia	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MOVICOL (Other drug) **Reason:** Depression
Batch: **Started:** **Stopped:**

MS CONTIN (Other drug) **Reason:** Pain
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:** Essential benign hypertension
Tablet 1.5 Milligram Daily Oral
Batch: **Started:** 06/03/2006 **Stopped:** 13/03/2006 0

LASIX (Suspected) **Reason:** Essential benign hypertension
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 218053 **Seq:** 1 **Gender:** F
Reported: 05/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 79
Onset Date: 09/03/2006 **DOB:** 16/04/1926
Outcome: Recovered 15/03/2006 **Causality:** Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 218304 **Seq:** 1 **Gender:** F
Reported: 12/05/2006 **Weight:** 55.00
Hospitalisation: **Age:** 45
Onset Date: 25/04/2006 **DOB:** 10/06/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Caused or prolonged inpatient hospitalisation	Patient experienced headaches, hands tremor, dizziness, 1 week after starting Avanza	Ceased Avanza
Dizziness	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Other drug) **Reason:** Unspecified schizophrenia
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 13/02/2006 **Stopped:**

OROXINE (Other drug) **Reason:** Myxedema
Tablet 50.0 Microgram Daily Oral
Batch: **Started:** 30/05/2005 **Stopped:**

IMOVANE (Other drug) **Reason:** Specific disorders of sleep
Tablet 7.5 Milligram Daily Oral
Batch: **Started:** 13/02/2006 **Stopped:**

AVANZA (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 219080 **Seq:** 1 **Gender:** F
Reported: 09/06/2006 **Weight:** 85.00
Hospitalisation: **Age:** 28
Onset Date: 25/02/2006 **DOB:** 23/10/1977
Outcome: Recovered 17/04/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice		Patient developed jaundice.	Avanza ceased.

Medicine Details:

EPILIM (Other drug) **Reason:** Other&unspecified epilepsy
1.0 Gram
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 20/01/2006 **Stopped:** 25/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219200 **Seq:** 1
Reported: 16/06/2006
Hospitalisation:
Onset Date: 04/06/2006
Outcome: Recovered with sequelae

Gender: M
Weight: 80.00
Age: 54
DOB: 17/10/1951
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction	Incapacity/disability	Photosensitive rash of face and hand approx 11 days after commencing the drug	Ceased drug.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet | Milligram | Daily | Oral

Batch: **Started:** 25/05/2006 **Stopped:** 06/06/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219234 **Seq:** 1
Reported: 19/06/2006
Hospitalisation: Admitted to hospital
Onset Date: 30/03/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 78
DOB: 16/04/1927
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient presented following a fall -	Mirtazipine ceased. Fluid restriction, investigation of

Medicine Details:

ALENDRONATE SODIUM (Other drug) **Reason:** Osteoporosis

Tablet 70.0 Milligram Weekly Oral

Batch: **Started:** **Stopped:** Ongoing.

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 29/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/06/2006	Sodium		30/03/2006	212	(Na+ = 117)
19/06/2006	Sodium		31/03/2006	123	(Na+ = 117)
19/06/2006	Sodium		01/04/2006	118	(Na+ = 117)
19/06/2006	Sodium		03/04/2006	125	(Na+ = 117)

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219287 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 77.00
Hospitalisation: **Age:** 45
Onset Date: 14/06/2006 **DOB:** 25/09/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Swelling face	Incapacity/disability	swelling of face and eyes	supportive
Eye swelling	Incapacity/disability		

Medicine Details:

Avanza Soltab (Suspected) **Reason:** Depression

Tablet 30.0 Milligram 1 time Oral

Batch: **Started:** 14/06/2006 **Stopped:** 15/06/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219377 **Seq:** 1
Reported: 21/06/2006
Hospitalisation:
Onset Date: 17/06/2006
Outcome: Recovered with sequelae

Gender: M
Weight: 0.00
Age: 54
DOB: 25/10/1951
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction Hypersensitivity	Life	Patient experienced an allergic reaction (dry skin with white sores on neck and back) and subsequently had 2 separate heart attacks	Stent

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 14/06/2006 **Stopped:** 17/06/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of severe head injuries with subsequent frontal lobe syndrome and mood disorder. Diabetes, overweight, increased blood sugars and triglycerides. Also taking olanzapine, metformin and telmisartan.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219599 **Seq:** 1 **Gender:** M
Reported: 03/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 45
Onset Date: 18/05/2006 **DOB:** 24/07/1960
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Night blindness		The patient noticed over the next three weeks that he lost his night vision. His	Remeron SolTab was

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 18/05/2006 **Stopped:** 07/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219733 **Seq:** 1 **Gender:** F
Reported: 06/07/2006 **Weight:** 65.00
Hospitalisation: **Age:** 71
Onset Date: 13/06/2006 **DOB:** 20/05/1935
Outcome: Recovered 15/06/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Patient could not wake next day. Took 2 days for excessive somnolence to wear off.	Avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram 1 time Oral
Batch: **Started:** 13/06/2006 **Stopped:** 13/06/2006

TEMAZE (Suspected) **Reason:** Specific disorders of sleep
10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219772 **Seq:** 1 **Gender:** F
Reported: 06/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 77Y
Onset Date: 04/04/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Pateint experienced hyponatreamia, lethargy with confusion.	Fluid restricted.
Confusional state	Caused or prolonged inpatient hospitalisation		
Lethargy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MINAX (Other drug) **Reason:** Otr&nos disord of heart rhythm
Batch: **Started:** **Stopped:**

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
Batch: **Started:** **Stopped:**

SOMAC (Other drug) **Reason:** Other diseases of esophagus
Batch: **Started:** **Stopped:**

COUMADIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/07/2006	Sodium		11/02/2006	109	
06/07/2006	Sodium		16/02/2006	123	
06/07/2006	Sodium		04/04/2006	119	
06/07/2006	Sodium		08/04/2006	135	

Additional Information:

Report 219770 is the first sequence to this report.

Report Detail

Case Number: 219772 **Seq:** 1 **Gender:** F
Reported: 06/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 77Y
Onset Date: 04/04/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ALPRIM (Other drug)			**Reason:**	Othr diseases of urinary tract
Batch:	**Started:**		**Stopped:**	
Mirtazon (Suspected)			**Reason:**	Depression
Tablet	15.0 Milligram	Daily		Oral
Batch:	**Started:**	16/02/2006	**Stopped:**	

Laboratory Investigations:

Additional Information:

Report 219770 is the first sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219790 **Seq:** 1
Reported: 07/07/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 74
DOB: 13/06/1932
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus inadequate cor Medication error		Patient given Avanza Soltab by pharmacist by error and control of blood sugar level's, patient very arratic mostly high. Settled when correct Avanza received.	

Medicine Details:

ACIMAX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ACTOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CELEBREX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CALTRATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219790 **Seq:** 1
Reported: 07/07/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 74
DOB: 13/06/1932
Causality: Causality probable

Reaction Detail

Medicine Details:

LASIX (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
NORVASC (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
OXAZEPAM (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
Simvar (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 219790 **Seq:** 1
Reported: 07/07/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 74
DOB: 13/06/1932
Causality: Causality probable

Reaction Detail

Medicine Details:

Avanza Soltab (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 219925 **Seq:** 1 **Gender:** F
Reported: 11/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 89
Onset Date: 25/06/2006 **DOB:** 22/05/1917
Outcome: Recovered 27/06/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Patient experienced bilateral leg oedema.	

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:** Pulmonary embolism&infarction
Batch: **Started:** **Stopped:**

FELODIPINE (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

CANDESARTAN CILEXETIL (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

VENTOLIN (Other drug) **Reason:** Otr respiratory systm diseases
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 219925 **Seq:** 1 **Gender:** F
Reported: 11/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 89
Onset Date: 25/06/2006 **DOB:** 22/05/1917
Outcome: Recovered 27/06/2006 **Causality:** Causality probable

Reaction Detail

Medicine Details:

PREDNISOLONE (Other drug)			**Reason:**	Otr respiratory systm diseases	
Batch:	**Started:**			**Stopped:**	
AVANZA (Suspected)			**Reason:**	Depression	
Tablet	15.0	Milligram	Daily		Oral
Batch:	**Started:**	20/06/2006		**Stopped:**	25/06/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220172 **Seq:** 1 **Gender:** M
Reported: 18/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 31Y
Onset Date: 04/07/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysarthria Agitation Insomnia Somnolence		patient was slurring his words and was like a "zombie", he was talking to himself and shouting. he did not sleep well.	reduced dose to 30mg

Medicine Details:

NUROFEN PLUS (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Axit (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 04/07/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220295 **Seq:** 1 **Gender:** F
Reported: 24/07/2006 **Weight:** 74.00
Hospitalisation: **Age:** 52
Onset Date: 15/05/2006 **DOB:** 14/07/1953
Outcome: Recovered 07/07/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperlipidaemia	Life	Patient experienced massive hyperlipidaemia, mild pancreatitis reaction, facial swelling, anorexia, malaise and general "unwell". There was evidence of cholestasis and some evidence of pancytopenia. There were minor rises in serum lipase which are difficult to interpret. Developed significant hepatotoxicity.	Avanza ceased.
Anorexia	Life		
Blood albumin increased	Life		
Blood cholesterol increased	Life		
Blood triglycerides increased	Life		
Cholestasis	Life		

Medicine Details:

AVAPRO HCT 300/12.5 (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Oral
Batch: **Started:** **Stopped:**

CENTRUM TABLETS (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Oral
Batch: **Started:** **Stopped:**

KLIOVANCE (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Oral
Batch: **Started:** **Stopped:**

NEURONTIN (Other drug) **Reason:**
Capsule 1.5 Gram Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/07/2006	ALT = SGPT	0 - 40	04/11/2005	46	ALT rising from 46 to 233.
24/07/2006	ALT = SGPT	0 - 40	30/06/2006	233	ALT rising from 46 to 233.
24/07/2006	ALT = SGPT	0 - 40	05/07/2006	77	ALT rising from 46 to 233.
24/07/2006	ALT = SGPT	0 - 40	07/07/2006	72	ALT rising from 46 to 233.
24/07/2006	ALT = SGPT	0 - 40	13/07/2006	41	ALT rising from 46 to 233.
24/07/2006	Albumin	38 - 55	04/11/2005	44	Serum albumin falling from 44 to a low of 31.
24/07/2006	Albumin	38 - 55	05/07/2006	33	Serum albumin falling from 44 to a low of 31.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220295 **Seq:** 1 **Gender:** F
Reported: 24/07/2006 **Weight:** 74.00
Hospitalisation: **Age:** 52
Onset Date: 15/05/2006 **DOB:** 14/07/1953
Outcome: Recovered 07/07/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatotoxicity	Life		
Lipase increased	Life		
Liver function test abnormal	Life		
Malaise	Life		
Pancreatitis	Life		
Pancytopenia	Life		
Swelling face	Life		

Medicine Details:

PYRIDOXINE HYDROCHLORIDE (Other drug) **Reason:**
Tablet 100.0 Milligram Oral
Batch: **Started:** **Stopped:**

RIVOTRIL (Other drug) **Reason:**
Tablet 2.0 Milligram Oral
Batch: **Started:** **Stopped:**

THIAMINE HYDROCHLORIDE (Other drug) **Reason:**
Tablet 100.0 Milligram Oral
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/07/2006	Albumin	38 - 55	13/07/2006	37	Serum albumin falling from 44 to a low of 31.
24/07/2006	Albumin	38 - 55	07/07/2006	40	Serum albumin falling from 44 to a low of 31.
24/07/2006	Albumin	38 - 55	30/06/2006	31	Serum albumin falling from 44 to a low of 31.
24/07/2006	Bilirubin	0 - 20	04/11/2005	9	
24/07/2006	Bilirubin	0 - 20	05/07/2006	17	
24/07/2006	Bilirubin	0 - 20	30/06/2006	24	
24/07/2006	Bilirubin	0 - 20	07/07/2006	26	

Additional Information:

Report Detail

Case Number: 220295 **Seq:** 1 **Gender:** F
Reported: 24/07/2006 **Weight:** 74.00
Hospitalisation: **Age:** 52
Onset Date: 15/05/2006 **DOB:** 14/07/1953
Outcome: Recovered 07/07/2006 **Causality:** Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected)			**Reason:** Depression	
Tablet	30.0 Milligram		Daily	Oral
Batch:	**Started:** 15/04/2006		**Stopped:** 03/07/2006	
ALCOHOL (Suspected)			**Reason:**	
	2.0 Unit		Daily	Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/07/2006	Bilirubin	0 - 20	13/07/2006	-	
24/07/2006	Cholesterol	3.9 - 5.5	04/11/2005	6.8	Cholesterol had jumped from 6.8 to 28.0.
24/07/2006	Cholesterol	3.9 - 5.5	07/07/2006	16.4	Cholesterol had jumped from 6.8 to 28.0.
24/07/2006	Cholesterol	3.9 - 5.5	30/06/2006	28.0	Cholesterol had jumped from 6.8 to 28.0.
24/07/2006	Cholesterol	3.9 - 5.5	13/07/2006	12.2	Cholesterol had jumped from 6.8 to 28.0.
24/07/2006	Erythrocyte	0 - 31	04/11/2005	38	
24/07/2006	Erythrocyte	0 - 31	13/07/2006	58	

Additional Information:

Report Detail

Case Number: 220295 **Seq:** 1 **Gender:** F
Reported: 24/07/2006 **Weight:** 74.00
Hospitalisation: **Age:** 52
Onset Date: 15/05/2006 **DOB:** 14/07/1953
Outcome: Recovered 07/07/2006 **Causality:** Causality possible

Reaction Detail

Medicine Details:

AVAPRO HCT 300/12.5 (Other drug)			**Reason:**	
Tablet	1.0	Dose Unspecified		Oral
Batch:	**Started:**		**Stopped:**	
CENTRUM TABLETS (Other drug)			**Reason:**	
Tablet	1.0	Dose Unspecified		Oral
Batch:	**Started:**		**Stopped:**	
KLIOVANCE (Other drug)			**Reason:**	
Tablet	1.0	Dose Unspecified		Oral
Batch:	**Started:**		**Stopped:**	
NEURONTIN (Other drug)			**Reason:**	
Capsule	1.5	Gram		Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/07/2006	Erythrocyte	0 - 31	07/07/2006	82	
24/07/2006	Erythrocyte	0 - 31	30/06/2006	2	
24/07/2006	Erythrocyte	0 - 31	05/07/2006	75	
24/07/2006	GGT = SGGT =	0 - 45	04/11/2005	518	GGT rising from a background of 518 up to 1343.
24/07/2006	GGT = SGGT =	0 - 45	05/07/2006	1289	GGT rising from a background of 518 up to 1343.
24/07/2006	GGT = SGGT =	0 - 45	07/07/2006	1343	GGT rising from a background of 518 up to 1343.
24/07/2006	GGT = SGGT =	0 - 45	13/07/2006	645	GGT rising from a background of 518 up to 1343.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220295 **Seq:** 1 **Gender:** F
Reported: 24/07/2006 **Weight:** 74.00
Hospitalisation: **Age:** 52
Onset Date: 15/05/2006 **DOB:** 14/07/1953
Outcome: Recovered 07/07/2006 **Causality:** Causality possible

Reaction Detail

Medicine Details:

PYRIDOXINE HYDROCHLORIDE (Other drug)			**Reason:**	
Tablet	100.0	Milligram		Oral
Batch:	**Started:**		**Stopped:**	
RIVOTRIL (Other drug)			**Reason:**	
Tablet	2.0	Milligram		Oral
Batch:	**Started:**		**Stopped:**	
THIAMINE HYDROCHLORIDE (Other drug)			**Reason:**	
Tablet	100.0	Milligram		Oral
Batch:	**Started:**		**Stopped:**	
PANADEINE FORTE (Suspected)			**Reason:**	
Tablet				Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/07/2006	Haemoglobin	119 - 160	04/11/2005	128	
24/07/2006	Haemoglobin	119 - 160	13/07/2006	108	
24/07/2006	Haemoglobin	119 - 160	07/07/2006	112	
24/07/2006	Haemoglobin	119 - 160	30/06/2006	133	
24/07/2006	Haemoglobin	119 - 160	05/07/2006	99	
24/07/2006	SAP = ALP	30 - 115	01/11/2005	138	
24/07/2006	SAP = ALP	30 - 115	30/06/2006	262	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220295 **Seq:** 1 **Gender:** F
Reported: 24/07/2006 **Weight:** 74.00
Hospitalisation: **Age:** 52
Onset Date: 15/05/2006 **DOB:** 14/07/1953
Outcome: Recovered 07/07/2006 **Causality:** Causality possible

Reaction Detai

Medicine Details:

AVANZA (Suspected)			**Reason:** Depression	
Tablet	30.0 Milligram		Daily	Oral
Batch:	**Started:** 15/04/2006		**Stopped:** 03/07/2006	
ALCOHOL (Suspected)			**Reason:**	
	2.0 Unit		Daily	Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/07/2006	SAP = ALP	30 - 115	07/07/2006	234	
24/07/2006	SAP = ALP	30 - 115	13/07/2006	-	
24/07/2006	SAP = ALP	30 - 115	05/07/2006	228	
24/07/2006	Triglyceride	0.5 - 1.7	04/11/2005	1.4	Triglycerides from 1.4 to 116.0.
24/07/2006	Triglyceride	0.5 - 1.7	30/06/2006	118.0	Triglycerides from 1.4 to 116.0.
24/07/2006	Triglyceride	0.5 - 1.7	07/07/2006	3.6	Triglycerides from 1.4 to 116.0.
24/07/2006	Triglyceride	0.5 - 1.7	13/07/2006	1.1	Triglycerides from 1.4 to 116.0.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220379 **Seq:** 1 **Gender:** M
Reported: 26/07/2006 **Weight:** 68.00
Hospitalisation: **Age:** 48
Onset Date: 19/07/2006 **DOB:** 10/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Incapacity/disability	Had been on valproate (Epilim) 500mg bd until mid-June; this was reinstated on admission, and the dose escalated to 500mg mane/1000mg nocte on 13 July.	
Musculoskeletal stiffness	Incapacity/disability	subjectively restless, panicky, stiff and shaky, and was observed to have bradykinesia, parkinsonian gait (but normal muscle tone), confusion, mild upper limb ataxia (clumsiness handling dinner plate etc) and a slight flap/tremor. valproate level (992 micromol/L, 5h post mane dose) and ammonia level (195 micromol/L) were elevated on 20 July. Patient was exquisitely sensitive to 5mg diazepam stat dose on 19 July.	Patient was exquisitely sensitive to 5mg diazepam stat dose on 19 July., Valproate was ceased immediately on clinical suspicion and olanzapine reducted to 7.5mg. Carnitine supplementation to be commenced when available, after repeat blood sample for valproate/carnitine levels

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
45.0 Milligram
Batch: **Started:** **Stopped:**

OLANZAPINE (Suspected) **Reason:**
10.0 Milligram
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:** Unspecified neurosis
Tablet 1.5 Gram Alternating-other Oral
Batch: unknown **Started:** 12/07/2006 **Stopped:** 20/07/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/07/2006	Other data				Investigations revealed normal FBC, EUC and LFT, but the valproate level (992 micromol/L, 5h post mane dose) and ammonia level (195 micromol/L) were elevated on 20 July.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220379 **Seq:** 1 **Gender:** M
Reported: 26/07/2006 **Weight:** 68.00
Hospitalisation: **Age:** 48
Onset Date: 19/07/2006 **DOB:** 10/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ammonia increased	Incapacity/disability		
Asterixis	Incapacity/disability		
Bradykinesia	Incapacity/disability		
Confusional state	Incapacity/disability		
Coordination abnormal	Incapacity/disability		
Drug level above therapeutic	Incapacity/disability		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
45.0 Milligram
Batch: **Started:** **Stopped:**

OLANZAPINE (Suspected) **Reason:**
10.0 Milligram
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:** Unspecified neurosis
Tablet 1.5 Gram Alternating-other Oral
Batch: unknown **Started:** 12/07/2006 **Stopped:** 20/07/2006 0

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 220379 **Seq:** 1 **Gender:** M
Reported: 26/07/2006 **Weight:** 68.00
Hospitalisation: **Age:** 48
Onset Date: 19/07/2006 **DOB:** 10/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Panic attack	Incapacity/disability		
Parkinsonian gait	Incapacity/disability		
Restlessness	Incapacity/disability		
Tremor	Incapacity/disability		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
45.0 Milligram
Batch: **Started:** **Stopped:**

OLANZAPINE (Suspected) **Reason:**
10.0 Milligram
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:** Unspecified neurosis
Tablet 1.5 Gram Alternating-other Oral
Batch: unknown **Started:** 12/07/2006 **Stopped:** 20/07/2006 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220495 **Seq:** 1
Reported: 01/08/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 06/03/2006
Outcome: Not yet recovered

Gender: M
Weight: 86.00
Age: 36
DOB: 30/06/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperlipidaemia		Hyperlipidaemia.	

Medicine Details:

Kivexa (Other drug) **Reason:** Hiv infection
1.0 Dose Unspecified
Batch: **Started:** 01/01/2006 **Stopped:**

VIRAMUNE (Other drug) **Reason:** Hiv infection
400.0 Milligram
Batch: **Started:** 31/03/1999 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Anxiety neurosis
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 12/12/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/08/2006	Other data				17/08/04 - Fasting Lipids: Cholesterol 4.0 and Triglyceride 1.5. 06/03/06 - Fasting Lipids: Cholesterol 5.9 and Triglyceride 2.4. 20/06/06 - Fasting Lipids: Cholesterol 6.3 and Triglyceride 8.0.

Additional Information:

Confirmed severe hyperlipidaemia secondary to Mirtazapine seen in another of my HIV patients.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220511 **Seq:** 1 **Gender:** M
Reported: 01/08/2006 **Weight:** 80.00
Hospitalisation: **Age:** 77
Onset Date: 01/08/2006 **DOB:** 02/11/1928
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	syncope, bradycardia/hypotension	atropine/iv fluids
Bradycardia	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PRAZOSIN HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PERINDOPRIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SIMVASTATIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ALLOPURINOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220511 **Seq:** 1
Reported: 01/08/2006
Hospitalisation:
Onset Date: 01/08/2006
Outcome: Unknown

Gender: M
Weight: 80.00
Age: 77
DOB: 02/11/1928
Causality: Causality possible

Reaction Detail

Medicine Details:

INDAPAMIDE HEMIHYDRATE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
ATENOLOL (Suspected)		**Reason:**	
Batch:	**Started:**		**Stopped:**
MIRTAZAPINE (Suspected)		**Reason:**	Anxiety neurosis
	15.0 Milligram	Daily	Oral
Batch:	**Started:** 31/07/2006		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220512 **Seq:** 1
Reported: 01/08/2006
Hospitalisation:
Onset Date: 01/08/2006
Outcome: Unknown

Gender: M
Weight: 80.00
Age: 83
DOB: 26/09/1922
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	syncope	observation/admission

Medicine Details:

PRAZOSIN HYDROCHLORIDE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
NATRILIX (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
COVERSYL PLUS (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
METOPROLOL TARTRATE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220512 **Seq:** 1
Reported: 01/08/2006
Hospitalisation:
Onset Date: 01/08/2006
Outcome: Unknown

Gender: M
Weight: 80.00
Age: 83
DOB: 26/09/1922
Causality: Causality possible

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
15.0 Milligram 1 time Oral
Batch: 864541/899481 **Started:** 31/07/2006 **Stopped:** 01/08/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220538 **Seq:** 1
Reported: 02/08/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 10/07/2006
Outcome: Recovered

Gender: F
Weight: 56.00
Age: 41
DOB: 14/02/1965
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia		Akathisia	12/07/2006

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram 1 time Oral

Batch: **Started:** 10/07/2006 **Stopped:** 11/07/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220653 **Seq:** 1 **Gender:** M
Reported: 08/08/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 11/07/2006 **DOB:** 22/07/1967
Outcome: Recovered with sequelae 14/07/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Caused or prolonged inpatient hospitalisation	Acute onset of loss of right visual field, left side throbbing headache and homonymous hemianopia - upper more than lower.	aspirin and Panadol.
Headache	Caused or prolonged inpatient hospitalisation		
Hemianopia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Truvada (Suspected) **Reason:** Hiv infection
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 04/07/2006 **Stopped:** 0

Atazanavir Sulfate (Suspected) **Reason:** Hiv infection
Capsule 400.0 Milligram Daily Oral
Batch: **Started:** 04/07/2006 **Stopped:**

VALTREX (Suspected) **Reason:** Herpes simplex
Tablet 1.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/08/2006	Computerised				A computed tomography (CT) scan shoed an area of low density within the left occipital lobe, suspicious for infarction. A computed tomography angiography (CTA) showed no verterbral dissection and no evidence of vasculitis; other vessels were normal.
08/08/2006	Echocardiogram				An echocardiogram was normal.
08/08/2006	Electrocardiograph				An electrocardiogram (ECG) sowed normal sinus rhythm and no
08/08/2006	Magnetic				A magnetic resonance imaging (MRI) scan showed evidence of a recent infarct affecting the left occipital lobe and posterior left

Additional Information:

Report Detail

Case Number: 220653 **Seq:** 1 **Gender:** M
Reported: 08/08/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 11/07/2006 **DOB:** 22/07/1967
Outcome: Recovered with sequelae 14/07/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vertebral artery stenosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Truvada (Suspected) **Reason:** Hiv infection
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 04/07/2006 **Stopped:** 0

Atazanavir Sulfate (Suspected) **Reason:** Hiv infection
Capsule 400.0 Milligram Daily Oral
Batch: **Started:** 04/07/2006 **Stopped:**

VALTREX (Suspected) **Reason:** Herpes simplex
Tablet 1.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220734 **Seq:** 1 **Gender:** F
Reported: 11/08/2006 **Weight:** 74.00
Hospitalisation: Required a visit to the doctor **Age:** 26
Onset Date: 08/10/2005 **DOB:** 08/08/1979
Outcome: Recovered 11/10/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder Abnormal behaviour Aggression		Psychotic reaction lasting 3 days after 1 tab - abnormal behaviour, aggressive towards her children.	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram 1 time Oral

Batch: **Started:** 08/10/2005 **Stopped:** 08/10/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 220784 **Seq:** 1
Reported: 15/08/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 15/07/2005
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 41
DOB: 21/04/1964
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depressed mood Depression Drug withdrawal syndrome Suicidal ideation		Severe discontinuation S/E Avanza-3 days following ceasing-agitation, mania, with severe depressed mood and suicidal ideation-(mood worse when initally commenced Avanza)	Recommenced another antidepressant-Prothiaden with gradual improvement.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 15/01/2005 **Stopped:** 15/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 221141 **Seq:** 1 **Gender:** M
Reported: 28/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intestinal perforation	Caused or prolonged inpatient hospitalisation	Abdominal pains which was discovered to be a bowel perforation.	Surgical repair.
Abdominal pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

REMERON (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 221283 **Seq:** 1 **Gender:** F
Reported: 01/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 70Y
Onset Date: 03/08/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Caused or prolonged inpatient hospitalisation	Acute myocardial infarction.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

OXAZEPAM (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:** Depression
5.0 Milligram Daily Oral
Batch: **Started:** 02/08/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 221431 **Seq:** 1
Reported: 06/09/2006
Hospitalisation:
Onset Date: 15/06/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 80
DOB: 23/04/1926
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous	Caused or prolonged inpatient hospitalisation	Bullous pemphigoid.	Ceased Remeron, treatment with prednisolone.

Medicine Details:

REMERON (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 222102 **Seq:** 1 **Gender:** F
Reported: 29/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Drug interaction			

Medicine Details:

AVANZA (Suspected) **Reason:**
Batch: **Started:** L TERM **Stopped:** 0

EPILIM (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

MOBIC (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 222384 **Seq:** 1 **Gender:** F
Reported: 12/10/2006 **Weight:** 59.00
Hospitalisation: Required a visit to the doctor **Age:** 77
Onset Date: 14/09/2006 **DOB:** 20/02/1929
Outcome: Recovered 21/09/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Generalised myalgia	

Medicine Details:

ZESTRIL (Other drug) **Reason:** Essential benign hypertension
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 13/09/2006 **Stopped:** 14/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 222424 **Seq:** 1 **Gender:** F
Reported: 13/10/2006 **Weight:** 55.00
Hospitalisation: **Age:** 67
Onset Date: 06/09/2006 **DOB:** 02/05/1939
Outcome: Recovered 27/09/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema Paraesthesia		Oedema in hands and feet with associated paraesthesia.	Mirtazon ceased.

Medicine Details:

Mirtazon (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 05/09/2006 **Stopped:** 22/09/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 222566 **Seq:** 1 **Gender:** F
Reported: 18/10/2006 **Weight:** 51.00
Hospitalisation: **Age:** 20
Onset Date: 01/10/2006 **DOB:** 10/01/1986
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Rash bilateral in armpits, red not swollen making her skin look like elephant skin. Not painful	Decreasing Avanza and using steroid cream.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 19/09/2006 **Stopped:** 03/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 222568 **Seq:** 1 **Gender:** M
Reported: 18/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		New suicidal ideation 3/52 after commencing antidepressant	

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 29/09/2006 **Stopped:** 18/10/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 222756 **Seq:** 1 **Gender:** M
Reported: 30/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 62
Onset Date: **DOB:** 24/01/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intraocular pressure increased Eye pain Vision blurred		Intraocular pressure increased, blurred vision and eye pain.	The ophthalmologist drilled a hole in the cornea using a laster to relieve the pressure. Remeron withdrawn

Medicine Details:

REMERON (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 15/09/2006 **Stopped:** 15/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 222890 **Seq:** 1
Reported: 03/11/2006
Hospitalisation: Admitted to hospital
Onset Date: 04/10/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 84
DOB: 23/08/1922
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient had a seizure.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 03/10/2006 **Stopped:** 04/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 223316 **Seq:** 1
Reported: 17/11/2006
Hospitalisation: Admitted to hospital
Onset Date: 04/08/2006
Outcome: Unknown

Gender: M
Weight: 103.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal failure acute	Caused or prolonged inpatient hospitalisation	Acute renal failure, acute behavioural changes (encephalopathy): confusion and hallucinations with onset of acute renal failure on day 5 of therapy	Tri-weekly haemodialysis
Abnormal behaviour	Caused or prolonged inpatient hospitalisation		
Encephalopathy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CARBOPLATIN (Suspected) **Reason:**
Injection Intravenous
Batch: **Started:** **Stopped:** 0

ETOPOSIDE (Suspected) **Reason:**
Injection Intravenous
Batch: **Started:** **Stopped:** 0

DIFLUCAN (Suspected) **Reason:**
200.0 Milligram
Batch: **Started:** **Stopped:**

BACTRIM DS (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2006	Creatinine		02/08/2006	105 umol/L	
17/11/2006	Creatinine		08/08/2006	140 umol/L	
17/11/2006	Creatinine		22/08/2006	742 umol/L	

Additional Information:

Report Detail

Case Number: 223316 **Seq:** 1
Reported: 17/11/2006
Hospitalisation: Admitted to hospital
Onset Date: 04/08/2006
Outcome: Unknown

Gender: M
Weight: 103.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected)				**Reason:**		
Tablet	30.0	Milligram			Oral	
Batch:	**Started:**			**Stopped:**		
HOLOXAN (Suspected)				**Reason:**	Otr prim malig n lymphoid tisu	
Injection	12.0	Gram	Daily		Intravenous	
Batch: 5K433	**Started:** 31/07/2006			**Stopped:**	02/08/2006	0
HOLOXAN (Suspected)				**Reason:**	Otr prim malig n lymphoid tisu	
Injection	12.0	Gram	Daily		Intravenous	
Batch: 5J121	**Started:** 31/07/2006			**Stopped:**	02/08/2006	
MESNA (Suspected)				**Reason:**		
Injection	12.0	Gram	Daily		Intravenous	
Batch:	**Started:**			**Stopped:**		0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 223337 **Seq:** 1
Reported: 17/11/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 28/09/2006
Outcome: Not yet recovered

Gender: F
Weight: 90.00
Age: 31
DOB: 08/01/1975
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pharyngeal oedema Delirium Disturbance in attention Dizziness Dyspnoea Palatal oedema Pruritus Rash Somnolence		Throat swelling, vague/absent minded, sleepy, itchiness, rash, dizziness, delirium, back of tongue swollen (uvula oedema) and breathing difficulty	Ceased medication. Gargle

Medicine Details:

Mirtazon (Suspected) **Reason:**

Tablet 45.0 Milligram Daily Oral

Batch: **Started:** 26/09/2006 **Stopped:** 03/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 223580 **Seq:** 1 **Gender:** M
Reported: 28/11/2006 **Weight:** 75.00
Hospitalisation: **Age:** 47Y
Onset Date: 27/10/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Oedema peripheral		Patient has gained 5kg in one week after starting Mirtazon. Also has puffy fingers.	

Medicine Details:

Mirtazon (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 20/10/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 223702 **Seq:** 1 **Gender:** F
Reported: 01/12/2006 **Weight:** 0.00
Hospitalisation: **Age:** 77
Onset Date: 12/10/2006 **DOB:** 18/03/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia Arthralgia Nightmare		Myalgia, arthralgia and nightmares.	Avanza ceased.

Medicine Details:

WARFARIN SODIUM (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
LANOXIN PG (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
LIPITOR (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
MAGMIN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 223702 **Seq:** 1 **Gender:** F
Reported: 01/12/2006 **Weight:** 0.00
Hospitalisation: **Age:** 77
Onset Date: 12/10/2006 **DOB:** 18/03/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Medicine Details:

RAMIPRIL (Other drug)			**Reason:**	
Batch:	**Started:**		**Stopped:**	
AVANZA (Suspected)			**Reason:**	Depression
Tablet	30.0 Milligram	Daily		Oral
Batch:	**Started:**	21/09/2006	**Stopped:**	21/10/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 223813 **Seq:** 1
Reported: 06/12/2006
Hospitalisation:
Onset Date: 19/10/2006
Outcome: Not yet recovered

Gender: F
Weight: 84.00
Age: 38
DOB: 07/01/1968
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Painful lip and neck after commencing	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 19/10/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 224002 **Seq:** 1 **Gender:** F
Reported: 07/12/2006 **Weight:** 51.00
Hospitalisation: **Age:** 46Y
Onset Date: 14/10/2006 **DOB:**
Outcome: Recovered 15/10/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paradoxical drug reaction Aggression Amnesia Hallucination Sleep paralysis Sleep walking Suicidal ideation		Depression, suicidal thoughts, sleep paralysis/hallucinations, amnesia, aggression	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Batch: **Started:** 15/05/2006 **Stopped:** 15/07/2006

STILNOX (Suspected) **Reason:** Disturbance of sleep

Tablet 1.0 Dose Unspecified Daily Oral

Batch: **Started:** 15/07/2006 **Stopped:** 15/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 224477 **Seq:** 1 **Gender:** M
Reported: 09/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 74
Onset Date: 05/01/2007 **DOB:** 01/01/1933
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Caused or prolonged inpatient hospitalisation	Developed urinary retention which progressively worsened until hospital admission three days after starting treatment with mirtazapine.	Changed antidepressant, catheterisation.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 05/01/2007 **Stopped:** 08/01/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 224575 **Seq:** 1 **Gender:** F
Reported: 11/01/2007 **Weight:** 65.00
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 23/02/1975
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome		Restless legs at night.	Ceased mirtazapine.

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 04/06/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 224686 **Seq:** 1
Reported: 16/01/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 07/11/2006
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 64
DOB: 30/01/1942
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Irritability Tension		2nd week got very edgy and cranky. After 3 weeks stopped taking.	

Medicine Details:

LASIX (Other drug) **Reason:**
20.0 Milligram
Batch: **Started:** **Stopped:**

PARIET (Other drug) **Reason:**
20.0 Milligram
Batch: **Started:** **Stopped:**

TEMAZE (Other drug) **Reason:**
10.0 Milligram
Batch: **Started:** **Stopped:**

AVAPRO HCT 150/12.5 (Other drug) **Reason:**
150.0 Milligram
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 224686 **Seq:** 1
Reported: 16/01/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 07/11/2006
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 64
DOB: 30/01/1942
Causality: Causality possible

Reaction Detail

Medicine Details:

PARACETAMOL (Other drug)			**Reason:**	
	6.0 Dose Unspecified			
Batch:	**Started:**		**Stopped:**	
AVANZA (Suspected)			**Reason:**	
Tablet	15.0 Milligram	Daily		Oral
Batch:	**Started:** 31/10/2006		**Stopped:**	20/11/2006

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 224770 **Seq:** 1
Reported: 17/01/2007
Hospitalisation:
Onset Date: 05/12/2006
Outcome: Not yet recovered

Gender: M
Weight: 85.00
Age: 36
DOB: 17/11/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia, Asymptomatic.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 29/11/2006 **Stopped:** 02/12/2006

OLANZAPINE (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** 02/12/2006 **Stopped:** 06/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/01/2007	Neutrophils				Neutophils 1.0.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 224942 **Seq:** 1 **Gender:** F
Reported: 22/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: 01/11/2006 **DOB:** 16/11/1956
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia	Incapacity/disability	Patient using Remeron for depression and experienced Akathisia in association with Remeron. When doctor increased the dose patient was experiencing restlessness.	Remeron ceased.
Restlessness	Incapacity/disability		

Medicine Details:

REMERON (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 225055 **Seq:** 1
Reported: 24/01/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 25/07/2006
Outcome: Recovered

Gender: F
Weight: 75.00
Age: 65
DOB: 21/03/1941
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Palpitations Paradoxical drug reaction Restlessness		Jumping legs, then that worked right up the body including heart, 5 hours later still restless	Shower calmed her down.

Medicine Details:

LIPITOR (Other drug)		**Reason:**	
Batch:	**Started:**	**Stopped:**	
PARIET (Other drug)		**Reason:**	
Batch:	**Started:**	**Stopped:**	
AVANZA (Suspected)		**Reason:**	
Batch:	**Started:**	**Stopped:**	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 225379 **Seq:** 1
Reported: 01/02/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 23/11/2006
Outcome: Not yet recovered

Gender: M
Weight: 62.00
Age: 40
DOB: 27/09/1966
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Skin rash, arms & legs symmetrical. Always on both sides of the body.	

Medicine Details:

FAMVIR (Other drug) **Reason:**
Tablet 2.0 Dose Unspecified Oral
Batch: **Started:** 15/07/2006 **Stopped:**

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 15/07/2006 **Stopped:** 23/11/2006 0

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 23/11/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 225531 **Seq:** 1
Reported: 07/02/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 20/11/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 94Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	Cessation of mirtazapine, rabeprazole and maxolon.

Medicine Details:

RABEPRAZOLE SODIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

OXYCONTIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

MAXOLON (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/02/2007	Neutrophils				Neutrophils 1.46
07/02/2007	White blood cells				WBC 2.9

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 225531 **Seq:** 1
Reported: 07/02/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 20/11/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 94Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

RISEDRONATE SODIUM (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
ASASANTIN SR (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
MIRTAZAPINE (Suspected)		**Reason:**	
	7.5 Milligram	Daily	
Batch:	**Started:** 04/11/2006		**Stopped:** 20/11/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 226210 **Seq:** 1
Reported: 28/02/2007
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 29
DOB: 11/04/1977
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Convulsion		Patient stopped taking Remeron and experienced seizure and fits.	Remeron restarted at a

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 45.0 Milligram Daily Oral

Batch: **Started:** 15/10/2006 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 226493 **Seq:** 1 **Gender:** M
Reported: 09/03/2007 **Weight:** 97.00
Hospitalisation: Required a visit to the doctor **Age:** 23
Onset Date: 22/01/2007 **DOB:** 04/02/1983
Outcome: Recovered 04/02/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, auditory Hallucination, tactile		Auditory hallucinations while lying in bed preparing to go to sleep. Took Avanza 1 hour previously - on 31/01/07 - tactile hallucinations - felt like he was punched on the right shoulder.	Reduce dose to half 1 week.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 11/01/2007 **Stopped:** 04/02/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 226624 **Seq:** 1 **Gender:** M
Reported: 14/03/2007 **Weight:** 89.00
Hospitalisation: **Age:** 72
Onset Date: 27/01/2007 **DOB:** 30/09/1934
Outcome: Recovered 02/02/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash macular		Suspected widespread rash due to	

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AVAPRO HCT 300/12.5 (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

TEMAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANTOPRAZOLE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 226624 **Seq:** 1 **Gender:** M
Reported: 14/03/2007 **Weight:** 89.00
Hospitalisation: **Age:** 72
Onset Date: 27/01/2007 **DOB:** 30/09/1934
Outcome: Recovered 02/02/2007 **Causality:** Causality possible

Reaction Detail

Medicine Details:

THIAMINE (Other drug)		**Reason:**	
Batch:	**Started:**	**Stopped:**	
AMOXYCILLIN TRIHYDRATE (Suspected)		**Reason:**	
Batch:	**Started:**	**Stopped:**	0
MIRTAZAPINE (Suspected)		**Reason:**	Depression
	7.5 Milligram	Daily	
Batch:	**Started:** 26/01/2007	**Stopped:**	0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 226711 **Seq:** 1 **Gender:** F
Reported: 16/03/2007 **Weight:** 63.00
Hospitalisation: **Age:** 52Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus		caused ringing in the ears. Ringing has continued (for four months now) after	no known treatment available

Medicine Details:

AVANZA (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 227318 **Seq:** 1 **Gender:** F
Reported: 03/04/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 37Y
Onset Date: 16/02/2007 **DOB:**
Outcome: Recovered 19/02/2007 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration Dysphagia Metrorrhagia		Patient taking venlafaxine for the past 11 months for post natal depression, the dose had been increased but she still had suicidal thoughts so a low dose mirtazapine was added. Within 2 days she had extensive mouth ulcers, dyphagia and vaginal spotting.	Stopped mirtezapine.

Medicine Details:

EFEXOR (Other drug) **Reason:** Depression
450.0 Milligram Daily
Batch: **Started:** 15/04/2006 **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 14/02/2007 **Stopped:** 17/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 227527 **Seq:** 1
Reported: 10/04/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 02/03/2007
Outcome: Not yet recovered

Gender: F
Weight: 76.00
Age: 30
DOB: 18/02/1977
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain Arthralgia Bone pain Contusion Fatigue		Severe bone pain, unable to sleep, feels achey, exhausted.	

Medicine Details:

AVANZA (Suspected) **Reason:**

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 01/03/2007 **Stopped:** 04/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 227622 **Seq:** 1 **Gender:** M
Reported: 16/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Recovered 06/03/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise		Patient went to the doctor who prescribed Avanza 30mg and received Temaze 20mg instead of Stilnox. Took one dose of each and felt so bad he almost fell down some stairs.	Ceased all drugs.

Medicine Details:

STILNOX (Suspected) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 12/02/2007 **Stopped:** 04/03/2007

TEMAZE (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 05/03/2007 **Stopped:** 06/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 227670 **Seq:** 1 **Gender:** F
Reported: 18/04/2007 **Weight:** 55.00
Hospitalisation: **Age:** 15
Onset Date: 14/04/2007 **DOB:** 27/06/1991
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Swelling face			

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 12/04/2007 **Stopped:** 14/04/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 227961 **Seq:** 1 **Gender:** F
Reported: 26/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 76Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal distension Constipation		Patient experienced bloating and constipation after taking Avanza.	Avanza ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Anxiety neurosis
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 15/08/2006 **Stopped:** 15/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228054 **Seq:** 1 **Gender:** F
Reported: 30/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 72Y
Onset Date: 22/09/2006 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Repetitive speech	Caused or prolonged inpatient hospitalisation	Seizures - repetitive speech, confusional state and consciousness fluctuating.	Tramadol ceased and Sandomigran recommenced. Rhevtein commenced
Confusional state	Caused or prolonged inpatient hospitalisation		
Consciousness fluctuating	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMAL SR (Interaction) **Reason:** Migraine
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 28/09/2006

Axit (Interaction) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SANDOMIGRAN (Interaction) **Reason:** Migraine
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 08/09/2006 **Stopped:** 22/09/2006

NEXIUM (Other drug) **Reason:**
40.0 Milligram
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Noticable change in energy levels/behaviou after commencement of sandomigran - during hospital admission Tramadol ceased + sandomigran recommended.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228054 **Seq:** 1 **Gender:** F
Reported: 30/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 72Y
Onset Date: 22/09/2006 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jamais vu	Caused or prolonged inpatient hospitalisation		
Verbigeration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

NOTEN (Other drug) **Reason:**
50.0 Milligram
Batch: **Started:** **Stopped:**

COVERSYL PLUS (Other drug) **Reason:**
1.0 Dose Unspecified
Batch: **Started:** **Stopped:**

ISCOVER (Other drug) **Reason:**
75.0 Milligram
Batch: **Started:** **Stopped:**

MEGAFOL (Other drug) **Reason:**
0.5 Milligram
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Noticable change in energy levels/behaviou after commencement of sandomigran - during hospital admission Tramadol ceased + sandomigran recommended.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228231 **Seq:** 1 **Gender:** F
Reported: 07/05/2007 **Weight:** 77.00
Hospitalisation: **Age:** 58
Onset Date: 15/03/2007 **DOB:** 01/07/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Patient experienced intermittent arthralgia of various joints, both knees and elbows, at	Medication ceased.

Medicine Details:

AVANZA (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 09/03/2007 **Stopped:** 21/03/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228272 **Seq:** 1 **Gender:** F
Reported: 08/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 56Y
Onset Date: 15/08/2006 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vertigo Insomnia		Patient experienced head spinning, difficulty with sleep became worse, took 2 days to recover	

Medicine Details:

Axit (Suspected) **Reason:** Depression
Tablet 0.3 Dose Unspecified Daily Oral
Batch: **Started:** 15/08/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Then tried 1/4 tab with similar effect, 1 tablet in March 2007 with same result. Cert(re-chall).

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228295 **Seq:** 1
Reported: 26/04/2007
Hospitalisation:
Onset Date: 14/12/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 64
DOB: 26/08/1942
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Parkinsonism Gait spastic		Parkinsonism.	Started Sinemet100/25 tds.

Medicine Details:

BURINEX (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
WARFARIN SODIUM (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
KARVEA (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
NOTEN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous allergies: Codeine, EES, morphine, tramadol.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228295 **Seq:** 1
Reported: 26/04/2007
Hospitalisation:
Onset Date: 14/12/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 64
DOB: 26/08/1942
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 20/11/2006 **Stopped:** 14/12/2006

Laboratory Investigations:

Additional Information:

Previous allergies: Codeine, EES, morphine, tramadol.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228500 **Seq:** 1
Reported: 14/05/2007
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 50
DOB: 08/01/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT corrected		Patient had been using mirtazapine since november 2006.	Mirtazapine was reduced from 30 to 15 mg/day.

Medicine Details:

TIBOLONE (Other drug)			**Reason:**		
	2.5	Milligram	Daily		Oral
Batch:	**Started:** 30/01/2006		L TERM	**Stopped:**	
Rosuvastatin (Other drug)			**Reason:**		
	10.0	Milligram	Daily		Oral
Batch:	**Started:** 02/11/2006		L TERM	**Stopped:**	
MIRTAZAPINE (Suspected)			**Reason:**		
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/05/2007	Electrocardiograph				
14/05/2007	Other data		30/03/2007	CBP, LFT and	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228535 **Seq:** 1 **Gender:** U
Reported: 15/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 30/03/2007 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fluid retention Aggression Agitation Somnolence		Fluid retention, hyper somnolence, agitation and feeling aggressive.	

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 30/03/2007 **Stopped:** 08/04/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228537 **Seq:** 1 **Gender:** F
Reported: 15/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fluid retention		Acute fluid retention.	

Medicine Details:

AVANZA (Suspected) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 11/03/2007 **Stopped:** 17/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

11/3/07 gained 2kg in 6/7

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 228723 **Seq:** 1
Reported: 22/05/2007
Hospitalisation:
Onset Date: 07/04/2007
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 85
DOB: 09/07/1921
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation	6 DAYS AFTER COMMENCING mirtazapine patient experienced visual hallucinations, agitation, frustration, anger, disorientation and delirium	cease mirtazapine
Agitation	Caused or prolonged inpatient hospitalisation		
Anger	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CARVEDILOL HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FRUSEMIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PERINDOPRIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

DONEPEZIL HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient has dementia.

Report Detail

Case Number: 228723 **Seq:** 1
Reported: 22/05/2007
Hospitalisation:
Onset Date: 07/04/2007
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 85
DOB: 09/07/1921
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disorientation	Caused or prolonged inpatient hospitalisation		
Frustration	Caused or prolonged inpatient hospitalisation		
Hallucination, visual	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 01/04/2007 **Stopped:** 18/04/2007

Laboratory Investigations:

Additional Information:
patient has dementia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 229629 **Seq:** 1
Reported: 12/06/2007
Hospitalisation:
Onset Date: 09/06/2007
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 31Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fluid retention		gained 5kg over 4 days	
Weight increased		gained 5kg over 4 days	
Dizziness			
Sedation			

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression

30.0 Milligram Daily Oral

Batch: **Started:** 09/06/2007 **Stopped:** 11/06/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 230110 **Seq:** 1
Reported: 25/06/2007
Hospitalisation:
Onset Date: 25/05/2007
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 77
DOB: 17/03/1930
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia suspected to be due to	Lowered Avanza dose to 30mg.

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
100.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

RAMACE (Other drug) **Reason:** Essential benign hypertension
7.5 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

CARTIA (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 230110 **Seq:** 1
Reported: 25/06/2007
Hospitalisation:
Onset Date: 25/05/2007
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 77
DOB: 17/03/1930
Causality: Causality possible

Reaction Detail

Medicine Details:

AVANZA (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 230471 **Seq:** 1
Reported: 02/07/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 13/03/2006
Outcome: Recovered

Gender: F
Weight: 58.00
Age: 61
DOB: 04/05/1944
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Personality change Hypersensitivity Irritability Weight increased		Personality change, irritability, hypersensitivity, allergic reaction to Estalis patches, weight gain	Ceased mirtazapine.

Medicine Details:

ALDACTONE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SERETIDE ACCUHALER NOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

VENTOLIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ESTALIS CONTINUOUS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 230471 **Seq:** 1
Reported: 02/07/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 13/03/2006
Outcome: Recovered

Gender: F
Weight: 58.00
Age: 61
DOB: 04/05/1944
Causality: Causality probable

Reaction Detail

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AVANZA,Avanza Soltab,Axit,MIRTAZAPINE,Mirtazon,REMERON

Report Detail

Case Number: 230894 **Seq:** 1
Reported: 12/07/2007
Hospitalisation:
Onset Date: 02/04/2007
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 50
DOB: 08/01/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT corrected Oedema peripheral		Electrocardiogram QTcorrected interval prolonged and peripheral oedema.	Dose of mirtazapine was reduced from 30 to 15mg daily.

Medicine Details:

TIBOLONE (Other drug) **Reason:** Menopausal symptoms
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** 30/01/2006 L TERM **Stopped:** Continuing.

Rosuvastatin (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 01/11/2006 L TERM **Stopped:**

REMERON (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/11/2006 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/07/2007	Other data				Laboratory tests (CBP, LFT and electrolytes) performed on the 30 March 2007 had normal results.

Additional Information:

History of high cholesterol, normal pregnancy, para 1, 13 years ago and peripheral oedema as adverse event to mirtazapine 11/06. Before patient started treatment with mirtazapine, she had a normal QT.