THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 61224 **Seq:** 1 **Gender:** M
Reported: 16/06/1989 **Weight:** 60.00
Hospitalisation: **Age:** 72Y
Onset Date: 30/05/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice Urine analysis abnormal			

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 24/05/1989 **Stopped:** 07/06/1989

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				3/5 1/6 6/6 9/6 11/6 16/6 23/6 5/7 range alk phos: 76 608 940 790 659 461 227 99 (30-110) bilirubin: 9 145 268 161 121 56 39 25 (<17) ast: 20 106 119 80 65 34 18 32 (3-65) alt: 22 179 158 110 95 58 25 13 (<55)

Additional Information:

See original report for other drugs

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 67358 **Seq:** 1 **Gender:** F
Reported: 05/09/1990 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pharyngitis			

Medicine Details:

ALLEGRON (Suspected) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** 01/02/1990 **Stopped:** 28/07/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 67360 **Seq:** 1 **Gender:** F
Reported: 14/09/1990 **Weight:** 65.00
Hospitalisation: **Age:** 54Y
Onset Date: 29/07/1990 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Anorexia Fatigue Hepatic function abnormal Nausea Pruritus			

Medicine Details:

EES (Suspected) **Reason:** Cellulitis of finger and toe
Granules 4.0 Dose Unspecified Daily Oral
Batch: **Started:** 20/07/1990 **Stopped:** 25/07/1990

ESTIGYN (Suspected) **Reason:**
20.0 Microgram Daily
Batch: **Started:** **Stopped:** CONTIN

PROVERA (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

ALLEGRON (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Bilirubin 8 alp 287 ggt 127 ast 92 alt 182 on 31/07/90. all normal by 04/09/90

Additional Information:

Report Detail

Case Number: 75900 **Seq:** 1 **Gender:** F
Reported: 06/03/1992 **Weight:** 65.00
Hospitalisation: **Age:** 74
Onset Date: **DOB:** 04/11/1917
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased		High plasma level of nortriptyline.	

Medicine Details:

NORTAB (Interaction) **Reason:** Depression
25.0 Milligram Daily
Batch: **Started:** 22/08/1990 **Stopped:** 01/10/1991

NORTAB (Interaction) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** 04/09/1990 **Stopped:**

NORTAB (Interaction) **Reason:** Depression
100.0 Milligram Daily
Batch: **Started:** 05/10/1990 **Stopped:**

PROZAC (Interaction) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 23/10/1990 **Stopped:** 28/03/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				A twelve hour serum nortriptyline done on 13/12 showed a level

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 79618 **Seq:** 1 **Gender:** M
Reported: 21/09/1992 **Weight:** 72.00
Hospitalisation: **Age:** 58Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus			

Medicine Details:

NORTAB (Suspected) **Reason:** Anxiety neurosis
0.0
Batch: **Started:** 01/09/1989 **Stopped:** 28/12/1989

NORTAB (Suspected) **Reason:** Anxiety neurosis
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/04/1992 **Stopped:** 28/08/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 82379 **Seq:** 1 **Gender:** F
Reported: 19/01/1993 **Weight:**
Hospitalisation: **Age:**
Onset Date: 04/01/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration Neutropenia			

Medicine Details:

COGENTIN (Other drug) **Reason:**
500.0 Microgram Daily
Batch: **Started:** 18/07/1992 **Stopped:** CONTIN

STELAZINE (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 24/06/1992 **Stopped:** 05/01/1993

NORTAB (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** 22/12/1992 **Stopped:** 05/01/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils	2.0 - 8	04/01/1993	1.8	
	White blood cells		04/01/1993	4.0	

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 82643 **Seq:** 1 **Gender:** M
Reported: 03/02/1993 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dry mouth Dysphagia Mouth ulceration			

Medicine Details:

NORTAB (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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 84422 **Seq:** 1
Reported: 04/05/1993
Hospitalisation: Admitted to hospital
Onset Date: 13/06/1992
Outcome: Recovered

Gender: F
Weight:
Age: 58
DOB: 31/08/1933
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Flushing Hyperhidrosis Supraventricular tachycardia			

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 86158 **Seq:** 1 **Gender:** F
Reported: 20/07/1993 **Weight:** 75.00
Hospitalisation: **Age:** 75Y
Onset Date: 15/06/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Confusional state Drug level increased Leukocytosis Pyrexia			

Medicine Details:

PETHIDINE HYDROCHLORIDE (Interaction) **Reason:** Pain
Injection 225.0 Milligram Total Intramuscular
Batch: **Started:** 14/06/1992 **Stopped:** 15/06/1992

NORTAB (Interaction) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 01/01/1992 **Stopped:** 21/06/1992

AURORIX (Other drug) **Reason:** Depression
6.0 Dose Unspecified Daily
Batch: **Started:** 20/05/1993 **Stopped:**

LITHICARB (Other drug) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 01/06/1993 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level	100-200			Serum nortriptyline was 500.

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 88300 **Seq:** 1 **Gender:** F
Reported: 04/10/1993 **Weight:**
Hospitalisation: **Age:** 73Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Drug level increased Malaise			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

NORTRIPTYLINE HYDROCHLORIDE (Interaction) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:** 2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				12-hours serum test for nortriptyline showed a level of 470 ug/l. after two months of taking 50mg of nortriptyline nightly the patient's serum drug level was 117 ug/l.

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 90075 **Seq:** 1 **Gender:** F
Reported: 24/12/1993 **Weight:** 54.00
Hospitalisation: **Age:** 31Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 09/08/1993 **Stopped:** 30/08/1993

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/04/1992 **Stopped:** 30/08/1993

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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 92023 **Seq:** 1 **Gender:** M
Reported: 05/04/1994 **Weight:**
Hospitalisation: **Age:** 63Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Nocturnal myoclonic jerks	

Medicine Details:

ALLEGRON (Suspected) **Reason:** Depression

Oral application 75.0 Milligram Daily Oral

Batch: **Started:** 15/09/1993 **Stopped:** 10/03/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 96635 **Seq:** 1 **Gender:** F
Reported: 24/10/1994 **Weight:** 60.00
Hospitalisation: **Age:** 42Y
Onset Date: 29/08/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Delirium Depersonalisation Hyperventilation Malaise			

Medicine Details:

ALPRAZOLAM (Other drug) **Reason:** Anxiety neurosis
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 08/08/1994 **Stopped:** 29/08/1994

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 29/08/1994 **Stopped:** 29/08/1994

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Oral application 100.0 Milligram Daily Oral
Batch: **Started:** 08/08/1994 **Stopped:** 29/08/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax ceased and recommenced later with no effect - without nortriptyline.

Report Detail

Case Number: 97369 **Seq:** 1 **Gender:** M
Reported: 28/11/1994 **Weight:** 47.00
Hospitalisation: **Age:** 63Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

ISOPTIN (Suspected) **Reason:** Essential benign hypertension
120.0 Milligram Daily
Batch: **Started:** 26/03/1991 **Stopped:**

ALLEGRON (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 01/01/1986 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 98388 **Seq:** 1 **Gender:** F
Reported: 18/01/1995 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** 19/01/1994 **Stopped:** 02/02/1994

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:**
75.0 Milligram Daily
Batch: **Started:** 03/02/1994 **Stopped:** 14/02/1994

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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 103284 **Seq:** 1 **Gender:** F
Reported: 01/09/1995 **Weight:** 75.00
Hospitalisation: **Age:** 27Y
Onset Date: 26/05/1995 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

ALLEGRON (Suspected) **Reason:** Depression
0.0
Batch: **Started:** 01/11/1994 **Stopped:** 28/07/1995

ZOLOFT (Suspected) **Reason:** Depression
Tablet 3.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/11/1994 **Stopped:** 28/07/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 106286 **Seq:** 1 **Gender:** F
Reported: 07/02/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety			

Medicine Details:

AURORIX (Suspected) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:**

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

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 106944 **Seq:** 1 **Gender:** F
Reported: 07/03/1996 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: 27/02/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anaemia Neutropenia	 Severe		

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** 01/02/1996 **Stopped:** CONTIN

ENDONE (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

QUINIDINE BISULPHATE (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

FRAGMIN (Other drug) **Reason:**
5.0 Thousand Internat Daily
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bone marrow				Bone marrow aspirate and trephine 29/2/96 recovering white cell
	Haemoglobin		19/02/1996	114	
	Haemoglobin		27/02/1996	115	
	Haemoglobin		29/02/1996	132	
	Neutrophils		19/02/1996	7.5	
	Neutrophils		27/02/1996	0.2	
	Neutrophils		29/02/1996	0.7	

Additional Information:

Amitted 26/12/95 following motor vehicle injury with leg fracture and arterial injury. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 106944 **Seq:** 1
Reported: 07/03/1996
Hospitalisation:
Onset Date: 27/02/1996
Outcome: Not yet recovered

Gender: F
Weight:
Age: 18Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

METAMUCIL (Other drug)			**Reason:**		
	1.0	Dose Unspecified	Daily		
Batch:	**Started:**	01/01/1996		**Stopped:**	CONTIN
NORTRIPTYLINE HYDROCHLORIDE (Suspected)			**Reason:**	Pain	
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**	08/02/1996		**Stopped:**	26/02/1996
CARBAMAZEPINE (Suspected)			**Reason:**	Pain	
Tablet	200.0	Milligram	Daily		Oral
Batch:	**Started:**	12/02/1996		**Stopped:**	27/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets		19/02/1996	238	
	Platelets		27/02/1996	30	
	White blood cells		19/02/1996	4.0	
	White blood cells		27/02/1996	2.0	
	White blood cells		29/02/1996	2.7	

Additional Information:

Amitted 26/12/95 following motor vehicle injury with leg fracture and arterial injury. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 109716 **Seq:** 1 **Gender:** F
Reported: 04/07/1996 **Weight:**
Hospitalisation: **Age:** 79
Onset Date: **DOB:** 27/07/1916
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Vaginal infection Vomiting			Canesten, vagifem, mylanta, maxolon im and oral, famotidine

Medicine Details:

SEREPAX (Other drug) **Reason:** Specific disorders of sleep
30.0 Milligram Daily
Batch: **Started:** 27/05/1996 **Stopped:**

SORBITOL (Other drug) **Reason:** Constipation
30.0 Millilitre Daily
Batch: **Started:** 03/06/1996 **Stopped:**

CANESTEN (Suspected) **Reason:** Moniliasis
Ointment 0.0 Topical
Batch: **Started:** 28/05/1996 **Stopped:** 05/06/1996

TAMOXIFEN CITRATE (Suspected) **Reason:** Malignant neoplasm of breast
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 109716 **Seq:** 1
Reported: 04/07/1996
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight:
Age: 79
DOB: 27/07/1916
Causality: Causality possible

Reaction Detail

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (Suspected)			**Reason:** Depression	
	20.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	
COLOXYL WITH SENNA (Suspected)			**Reason:**	
	2.0 Dose Unspecified	Daily		
Batch:	**Started:** 24/05/1996		**Stopped:** 12/06/1996	

Laboratory Investigations:

Additional Information:

See original report for other drugs

Report Detail

Case Number: 111327 **Seq:** 1 **Gender:** M
Reported: 02/09/1996 **Weight:**
Hospitalisation: **Age:** 11Y
Onset Date: 23/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Tonic seizure.	

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 09/08/1996 **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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 113996 **Seq:** 1 **Gender:** F
Reported: 18/12/1996 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 26/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Infantile apnoeic attack			Intubated and bagged (positive pressure) - remained no spontaneous respiration 200 mcg narcan imi given with no effect. required oxygen for 5 days

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspected) **Reason:**
Injection 100.0 Milligram 1 time Intramuscular
Batch: **Started:** **Stopped:**

FENTANYL CITRATE (Suspected) **Reason:**
Injection 100.0 Microgram 1 time Epidural
Batch: **Started:** **Stopped:**

XYLOCAINE (Suspected) **Reason:**
10.0 Millilitre 1 time
Batch: **Started:** **Stopped:**

BUPIVACAINE HYDROCHLORIDE (Suspected) **Reason:**
Injection 10.0 Millilitre 1 time Epidural
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother treated for severe depression prior to and during pregnancy. usually takes prozac 20 x 2 tabs at 1600 and nortryptylline at 2100. on 26/11/96 mother took both prozac and nortriptylline at 1600, pethidine im at 1735, epidural fentanyl 100 mcg and 1% xylocaine 10mls at 1930. epidural top-up 10mls 0.25% bupivicaine at 2000. baby boy delivered 2030. failed to breathe spontaneously for 20 minutes post birth and did not cry. 200 mcg narcan imi given with no effect. required oxygen for 5 days

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 113996 **Seq:** 1 **Gender:** F
Reported: 18/12/1996 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 26/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PROZAC (Suspected)			**Reason:**	
	40.0	Milligram	Daily	
Batch:	**Started:**		L TERM	**Stopped:**
NORTRIPTYLINE HYDROCHLORIDE (Suspected)			**Reason:**	
	25.0	Milligram	Daily	
Batch:	**Started:**		L TERM	**Stopped:**

Laboratory Investigations:

Additional Information:

Mother treated for severe depression prior to and during pregnancy. usually takes prozac 20 x 2 tabs at 1600 and nortryptylline at 2100. on 26/11/96 mother took both prozac and nortriptylline at 1600, pethidine im at 1735, epidural fentanyl 100 mcg and 1% xylocaine 10mls at 1930. epidural top-up 10mls 0.25% bupivicaine at 2000. baby boy delivered 2030. failed to breathe spontaneously for 20 minutes post birth and did not cry. 200 mcg narcan imi given with no effect. required oxygen for 5 days

Report Detail

Case Number: 116647 **Seq:** 1 **Gender:** M
Reported: 09/04/1997 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: 02/03/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia Coordination abnormal Dry mouth Headache Somnolence Visual disturbance			

Medicine Details:

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

ROHYPNOL (Other drug) **Reason:**
0.5 Milligram Daily
Batch: **Started:** **Stopped:**

ALLEGRON (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 11/02/1997 **Stopped:**

AVENTYL (Suspected) **Reason:**
Oral application 30.0 Milligram Daily Oral
Batch: **Started:** 11/02/1997 **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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 122260 **Seq:** 1 **Gender:** M
Reported: 10/11/1997 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 02/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium Confusional state		Anticholinergic delirium	Nortriptyline ceased

Medicine Details:

MAXOLON (Other drug) **Reason:**
Oral application 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

VENTOLIN (Other drug) **Reason:** Otr respiratory systm diseases
Inhalation 20.0 Milligram Daily Inhalation
Batch: **Started:** **Stopped:** CONTIN

ATROVENT (Other drug) **Reason:** Otr respiratory systm diseases
Inhalation 2.0 Milligram Daily Inhalation
Batch: **Started:** **Stopped:** CONTIN

IMDUR (Other drug) **Reason:** Chron isch heart dis no hyper
60.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 122260 **Seq:** 1 **Gender:** M
Reported: 10/11/1997 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 02/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

PRINIVIL (Other drug)			**Reason:**		
	2.5	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
ASPIRIN (Other drug)			**Reason:**	Acute myocard infarc,no hypert	
	100.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
DIGOXIN (Other drug)			**Reason:**	Left ventricular failure	
	62.5	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
PULMICORT (Other drug)			**Reason:**		
Inhalation	400.0	Microgram	Daily	Inhalation	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 122260 **Seq:** 1 **Gender:** M
Reported: 10/11/1997 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 02/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Depression
100.0 Milligram Daily
Batch: **Started:** 25/10/1996 **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 122419 **Seq:** 1 **Gender:** U
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/07/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Vomiting			

Medicine Details:

AVENTYL (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 122504 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Muscles jumping	
Nausea		Nauseous	
Dizziness			
Vomiting			

Medicine Details:

AVENTYL (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred after taking tablets that were made in britian. no problem when patient reverted back to tablets that were manufactured in spain.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 123094 **Seq:** 1 **Gender:** F
Reported: 04/12/1997 **Weight:**
Hospitalisation: **Age:** AE
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysgeusia Breath odour Dry mouth		Bad taste	

Medicine Details:

ALLEGRON (Suspected) **Reason:**
Oral application 1.2 Milligram Daily Oral
Batch: **Started:** 01/09/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 123356 **Seq:** 1
Reported: 15/12/1997
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 61Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation Atrioventricular block Hypertension Tachycardia			Nortriptyline discontinued

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Oral application 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 126917 **Seq:** 1 **Gender:** M
Reported: 24/04/1998 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 29/12/1956
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia Dry mouth Tinnitus		Persistent tachycardia	

Medicine Details:

ALLEGRON (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 129083 **Seq:** 1 **Gender:** M
Reported: 10/07/1998 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gingival hyperplasia		Gingival overgrowth	Norvasc ceased

Medicine Details:

NORVASC (Suspected) **Reason:** Essential benign hypertension
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** 31/01/1998

ALLEGRON (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 130008 **Seq:** 1 **Gender:** M
Reported: 07/08/1998 **Weight:**
Hospitalisation: **Age:** 26Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare			

Medicine Details:

ALLEGRON (Suspected) **Reason:** Depression
Oral application 75.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Detail

Case Number: 137106 **Seq:** 1
Reported: 09/03/1999
Hospitalisation: Admitted to hospital
Onset Date: 13/02/1999
Outcome: Recovered

Gender: F
Weight:
Age: 83Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope Vertigo			Ceased allegron & norvasc.

Medicine Details:

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

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

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

NORVASC (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** 13/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: # l) fibula. patient history: ht, ihd, hiatus hernia, r) cea, l) carotid sterosis & direrticulosis.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 137106 **Seq:** 1
Reported: 09/03/1999
Hospitalisation: Admitted to hospital
Onset Date: 13/02/1999
Outcome: Recovered

Gender: F
Weight:
Age: 83Y
DOB:
Causality: Causality possible

Reaction Detai

Medicine Details:

ALLEGRON (Suspected)			**Reason:**	
	50.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	15/02/1999
BETALOC (Suspected)			**Reason:**	
	150.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Additional Information:

Sequelae: # l) fibula. patient history: ht, ihd, hiatus hernia, r) cea, l) carotid sterosis & direrticulosis.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 139957 **Seq:** 1 **Gender:** F
Reported: 27/05/1999 **Weight:**
Hospitalisation: **Age:** 81
Onset Date: 28/06/1998 **DOB:** 21/04/1917
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizziness past 3 years	Cease nortriptyline.

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Depression

0.0

Batch: **Started:** **Stopped:** 28/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs - paracetamol, temazepam, panadeine forte, coloxyl senna, heparin, madopar.

Report Detail

Case Number: 151804 **Seq:** 1 **Gender:** M
Reported: 17/04/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 14/03/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous Tongue oedema		Blisters on the tongue.	Allegron discontinued.

Medicine Details:

PREDNISONE (Suspected) **Reason:** Rash
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

ALLEGRON (Suspected) **Reason:** Depression
Tablet 12.5 Milligram Daily Oral
Batch: **Started:** 14/03/2000 **Stopped:** 14/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Shortly after taking half an allegron tablet, reactions occurred.

Report Detail

Case Number: 155068 **Seq:** 1 **Gender:** F
Reported: 20/07/2000 **Weight:**
Hospitalisation: **Age:** 90
Onset Date: 02/05/2000 **DOB:** 11/02/1910
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Orthostatic hypotension Syncope			Moduretic ceased.

Medicine Details:

MODURETIC (Suspected) **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 25/04/2000 **Stopped:** 02/05/2000

NICOTINIC ACID (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 02/05/2000

ALLEGRON (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 02/05/2000

LPV (Suspected) **Reason:**
Oral application 2.0 Gram Daily Oral
Batch: **Started:** 25/04/2000 **Stopped:** 02/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking lasix, caltrate, panamax, mogadon, solprin.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 156759 **Seq:** 1
Reported: 24/08/2000
Hospitalisation: Admitted to hospital
Onset Date: 27/06/2000
Outcome: Recovered

Gender: F
Weight:
Age: 57Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination			Diazepam and cyproheptadine.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:** 27/06/2000

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:** 27/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 30/6/00.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 159377 **Seq:** 1 **Gender:** F
Reported: 17/11/2000 **Weight:**
Hospitalisation: **Age:** 82Y
Onset Date: 06/11/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Urinary retention Vomiting			Patient hospitalised. allegron ceased

Medicine Details:

ALLEGRON (Suspected) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** 01/11/2000 **Stopped:** 08/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking diaformin, aspirin, adalat, prednisolone, metoprolol, frusemide, omeprazole, canesten, timoptol.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 163315 **Seq:** 1
Reported: 02/04/2001
Hospitalisation:
Onset Date: 02/03/2001
Outcome: Not yet recovered

Gender: F
Weight: 81.00
Age: 55Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Severe	Severe weight increase.	

Medicine Details:

ALLEGRON (Suspected) **Reason:**
100.0 Milligram Daily
Batch: **Started:** 01/10/2000 **Stopped:** 27/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Weight increase of 20kg.

Additional Information:

The dose start date is not necessarily 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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 164851 **Seq:** 1 **Gender:** M
Reported: 25/05/2001 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 26/04/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysgeusia Convulsion		Strange taste	Zyban ceased. patient

Medicine Details:

ZYBAN SR (Interaction) **Reason:** Depression
300.0 Milligram Daily
Batch: **Started:** 01/03/2001 **Stopped:** 26/04/2001

ALLEGRON (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electroencephalog				Eeg report 01/05/01 - there is a symmetrical and responsive 9-11 hertz alpha rythm together with a mild excess of 4-7 hertz hertz theta activity occuring bilaterally in the resting record. brief episodes of higher amplitute 1-2 hert z slow and 4-7 hertz theta activity occur over each hemisphere in the resting record. contin...

Additional Information:

Patient was also found to have an anterior dislocation of the left shoulder which was reduced. there is no previous history of epilepsy, childhood convulsions, head injury, birth trauma, meningoencephalitis or systemic disease. there is no family history of epilepsy. patient has been taking zyban sr for 6 weeks. the dose start date is not necessarily accurate but indicates the drug was sta rted sometime in the month.

Report Detail

Case Number: 164851 **Seq:** 1 **Gender:** M
Reported: 25/05/2001 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 26/04/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

ZYBAN SR (Interaction)			**Reason:** Depression	
	300.0 Milligram	Daily		
Batch:	**Started:** 01/03/2001		**Stopped:** 26/04/2001	
ALLEGRON (Interaction)			**Reason:**	
	20.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	
LITHIUM CARBONATE (Other drug)			**Reason:**	
	300.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	
THYROXINE SODIUM (Other drug)			**Reason:**	
	100.0 Microgram	Daily		
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electroencephalog				Contin... slow wave activity is more prominent during hyperventilation where there is a slight left hemisphere preponderance. no additional information is gained on photic simulation. conclusion: the record is abnormal and shows a non-specific dysrhythmia with paroxysmal features. slight lateralization of slow activity.

Additional Information:

Patient was also found to have an anterior dislocation of the left shoulder which was reduced. there is no previous history of epilepsy, childhood convulsions, head injury, birth trauma, meningoencephalitis or systemic disease. there is no family history of epilepsy. patient has been taking zyban sr for 6 weeks. the dose start date is not necessarily accurate but indicates the drug was sta rted sometime in the month.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 165724 **Seq:** 1 **Gender:** F
Reported: 25/06/2001 **Weight:** 52.00
Hospitalisation: **Age:** 18
Onset Date: 11/03/2001 **DOB:** 27/08/1982
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotension Orthostatic hypotension Tachycardia			

Medicine Details:

ALLEGRON (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 03/03/2001 **Stopped:** 29/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 1/5/2001. high sensitivity to low doses of ssri's, ie moclobemide.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 166820 **Seq:** 1 **Gender:** F
Reported: 24/07/2001 **Weight:**
Hospitalisation: **Age:** 76
Onset Date: 01/05/2000 **DOB:** 05/03/1924
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Dyskinesia		Patient presented with fall.	Ceased allergron and commenced pantoprazole.

Medicine Details:

ALLEGRON (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

RANI 2 (Suspected) **Reason:** Other diseases of esophagus
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking zocor, clopidogrel, coloxyl 120, psyllium huska.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 168519 **Seq:** 1 **Gender:** F
Reported: 19/09/2001 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 09/09/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination			Treated with haloperidol 1.5mg

Medicine Details:

KAPANOL (Suspected) **Reason:** Pain
Capsule 140.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Pain
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 16/08/2001 **Stopped:** CONTIN

GABAPENTIN (Suspected) **Reason:** Pain
Capsule 800.0 Milligram Daily Oral
Batch: **Started:** 24/08/2001 **Stopped:** CONTIN

RANITIDINE (Suspected) **Reason:** Other diseases of esophagus
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: metastatic breast cancer with brachial plexus lesion causing neuropathic pa.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 168519 **Seq:** 1
Reported: 19/09/2001
Hospitalisation:
Onset Date: 09/09/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 60Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

CLEXANE (Suspected)			**Reason:**	Phleb&thrombophleb lowr extrem	
Injection	90.0	Milligram	Daily	Intravenous	
Batch:	**Started:**	29/08/2001		**Stopped:**	CONTIN
DEXAMETHASONE (Suspected)			**Reason:**		
Oral application	4.0	Milligram	Daily	Oral	
Batch:	**Started:**	S TERM		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Patient history: metastatic breast cancer with brachial plexus lesion causing neuropathic pa.

Report Detail

Case Number: 169221 **Seq:** 1 **Gender:** F
Reported: 15/10/2001 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 28/08/2001 **DOB:**
Outcome: Unrelated death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination			Date of death 23/09/01 -

Medicine Details:

MAXOLON (Other drug) **Reason:** Nausea and vomiting
Oral application 0.0 Oral
Batch: **Started:** **Stopped:** 23/09/2001

DEXAMETHASONE (Other drug) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:** 23/09/2001

COLOXYL WITH SENNA (Other drug) **Reason:** Constipation
Oral application 0.0 Oral
Batch: **Started:** **Stopped:** 23/09/2001

FLAGYL (Other drug) **Reason:**
Cream 0.0 Topical
Batch: **Started:** **Stopped:** 23/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient with metastatic breast cancer.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 169221 **Seq:** 1 **Gender:** F
Reported: 15/10/2001 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 28/08/2001 **DOB:**
Outcome: Unrelated death **Causality:** Causality possible

Reaction Detail

Medicine Details:

SILVER SULPHADIAZINE (Other drug)			**Reason:**		
	0.0				
Batch:	**Started:**			**Stopped:**	
KAPANOL (Other drug)			**Reason:**	Pain	
Oral application	0.0				Oral
Batch:	**Started:**			**Stopped:**	23/09/2001
NORTRIPTYLINE HYDROCHLORIDE (Suspected)			**Reason:**	Pain	
Oral application	0.0				Oral
Batch:	**Started:**	16/08/2001		**Stopped:**	23/09/2001
CLEXANE (Suspected)			**Reason:**		
Injection	0.0				Subcutaneous
Batch:	**Started:**	28/08/2001		**Stopped:**	23/09/2001

Laboratory Investigations:

Additional Information:

Patient with metastatic breast cancer.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 169221 **Seq:** 1 **Gender:** F
Reported: 15/10/2001 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 28/08/2001 **DOB:**
Outcome: Unrelated death **Causality:** Causality possible

Reaction Detail

Medicine Details:

NEURONTIN (Suspected) **Reason:** Pain
Oral application 800.0 Milligram Daily Oral
Batch: **Started:** 01/08/2001 **Stopped:** 23/09/2001

Laboratory Investigations:

Additional Information:

Patient with metastatic breast cancer.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 177648 **Seq:** 1 **Gender:** F
Reported: 05/08/2002 **Weight:** 59.00
Hospitalisation: **Age:** 45
Onset Date: 01/05/2002 **DOB:** 11/07/1956
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gingival bleeding			

Medicine Details:

ALLEGRON (Suspected) **Reason:**
25.0 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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 183038 **Seq:** 1 **Gender:** F
Reported: 06/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 75
Onset Date: 19/08/2002 **DOB:** 08/02/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Serotonin Syndrome	Diazepam given 5mg prn. CT head done due to periods of loss of consciousness-NAD
Serotonin syndrome		Serotonin Syndrome	Diazepam given 5mg prn. CT head done due to periods of loss of consciousness-NAD
Muscle twitching		Serotonin Syndrome, aggitation, twitching occurred each morning.	Diazepam given 5mg prn. CT head done due to periods of loss of consciousness-NAD

Medicine Details:

TRAMAL SR (Interaction) **Reason:**
Tablet 200.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

ALLEGRON (Interaction) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HYPERICUM-ST JOHN'S WORT (Other drug) **Reason:** Depression
Daily Oral
Batch: **Started:** **Stopped:**

CELEBREX (Other drug) **Reason:**
Capsule 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

When Tramal and nortriptyline were ceased, symptoms improved.
Patient was also taking caltrate, Ferrous sulp sr, Vit e, Vit C.

Report Detail

Case Number: 185679 **Seq:** 1 **Gender:** F
Reported: 07/05/2003 **Weight:** 53.00
Hospitalisation: **Age:** 67
Onset Date: 15/08/2002 **DOB:** 19/12/1934
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paranoia	Required Visit to Doctor	Feeling of apprehension and terror/frantic	
Anxiety	Required Visit to Doctor		

Medicine Details:

ALLEGRON (Suspected) **Reason:** Otr mus rheum,fibrosit&myalgia
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 09/08/2002 **Stopped:**

ZOCOR (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 09/08/2002 **Stopped:** 17/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Coversyl and Iscover.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 186333 **Seq:** 1 **Gender:** F
Reported: 23/05/2003 **Weight:** 60.00
Hospitalisation: **Age:** 60Y
Onset Date: 13/11/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal impairment		Nephritis interstitial.	Prednisone

Medicine Details:

ROCALTROL (Suspected) **Reason:** Osteoporosis

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

ALLEGRON (Suspected) **Reason:** Anxiety neurosis

Tablet 75.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allegron was started sometime in September 2002, and stopped sometime in November 2002.
Rocaltrol was started sometime in February 2002 and stopped sometime in November 2002.
Patient was also taking Atacard, zocor, Valium.

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 197475 **Seq:** 1 **Gender:** F
Reported: 20/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: 11/02/2004 **DOB:** 16/06/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Attention deficit/hyperactivity disc Dizziness Paraesthesia Somnolence Tremor		Attention deficit disorder, drowsiness, light headedness, fine tremor and pins & needles in extremeties.	

Medicine Details:

ZOTON (Other drug) **Reason:**

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

ALLEGRON (Suspected) **Reason:**

Daily

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

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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 199273 **Seq:** 1 **Gender:** M
Reported: 21/07/2004 **Weight:** 90.00
Hospitalisation: **Age:** 58
Onset Date: **DOB:** 09/06/1946
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Agitated, voice changes and disoriented when driving around corners.	Ceasing Allergron.
Disorientation	Required Visit to Doctor		
Dysphonia	Required Visit to Doctor		

Medicine Details:

ALLEGRON (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 09/03/2004 **Stopped:** 20/03/2004

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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 210578 **Seq:** 1
Reported: 11/08/2005
Hospitalisation: Hospitalisation prolonged
Onset Date: 01/01/2005
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 49
DOB: 17/06/1955
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Encephalopathy	Caused or prolonged inpatient hospitalisation	Drug-induced encephalopathy with paranoid features where the combination of a tricyclic antidepressant and SNRI was implicated as the major cause.	Patient was transferred to Royal Melbourne Hospital
Paranoia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Interaction) **Reason:**
Capsule 225.0 Milligram Oral
Batch: **Started:** **Stopped:**

NORTRIPTYLINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet 175.0 Milligram Oral
Batch: **Started:** **Stopped:**

GABAPENTIN (Other drug) **Reason:**
1200.0 Milligram Oral
Batch: **Started:** **Stopped:**

AMANTADINE HYDROCHLORIDE (Other drug) **Reason:**
Capsule 200.0 Milligram Oral
Batch: **Started:** **Stopped:** 13/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 210578 **Seq:** 1
Reported: 11/08/2005
Hospitalisation: Hospitalisation prolonged
Onset Date: 01/01/2005
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 49
DOB: 17/06/1955
Causality: Causality possible

Reaction Detail

Medicine Details:

LAMOTRIGINE (Other drug)			**Reason:**		
Tablet	200.0	Milligram			Oral
Batch:	**Started:**			**Stopped:**	
COPAXONE (Other drug)			**Reason:**		
Injection			Daily		Subcutaneous
Batch:	**Started:**			**Stopped:**	
METHYSERGIDE MALEATE (Other drug)			**Reason:**		
Tablet	3.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	13/01/2005

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 214539 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 09/09/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Akathisia		The patient developed chronic serotonin syndrome and severe akathisia.	

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

NUROFEN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

VALIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

NORTRIPTYLINE HYDROCHLORIDE (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: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 214539 **Seq:** 1
Reported: 04/01/2006
Hospitalisation:
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 46
DOB: 09/09/1959
Causality: Causality possible

Reaction Detail

Medicine Details:

Lexapro (Suspected)		**Reason:**	
			Oral
Batch:	**Started:**		**Stopped:**
ZYPREXA (Suspected)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 214862 **Seq:** 1
Reported: 11/01/2006
Hospitalisation: Admitted to hospital
Onset Date: 09/11/2005
Outcome: Unknown

Gender: F
Weight: 53.00
Age: 20
DOB: 30/03/1985
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient presented to E.D. after experiencing a seizure.	EEG/for further investigation.

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** S TERM **Stopped:**

ALLEGRON (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No history of alcohol misuse or befrile convulsions.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALLEGRON,AVENTYL,NORTAB,NORTRIPTYLINE HYDROCHLORIDE

Report Detail

Case Number: 217242 **Seq:** 1
Reported: 10/04/2006
Hospitalisation: Admitted to hospital
Onset Date: 11/11/2005
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 42Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation	Patient experienced dizziness and palpitation. Started on half Allegron and then increased to 3 daily.	Withheld Northriptyline, started beta blocker Atenolol.
Palpitations	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ALLEGRON (Suspected) **Reason:**

87.5 Milligram Daily

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information: