

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 Detai

Preferred Term	Severity	Report Description	Treatment
Jaundice			
Urine analysis abnormal			

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (Suspected) Reason: Depression

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 24/05/1989
 3topped: 07/06/1989

Laboratory Investigations:

Date	Туре	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

Report Run 19/07/200 03:57PN Database: pusime ADRS004 Page 1 of 64



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:
Onset Date:
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pharyngitis			

Medicine Details:

ALLEGRON (Suspected) Reason: Depression

75.0 Milligram Daily

3atch: 3tarted: 01/02/1990 3topped: 28/07/1990

Laboratory Investigations:

Date	Туре	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.



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

Report De	etai	İ
-----------	------	---

 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 Detai

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

Medicine Details:

EES (Suspected)	Reas	on:	Cellulitis of fin	ger and toe	
Granules	4.0 Dose Unspecified	Daily		Oral	
3atch:	Started: 20/07/1990		Stopped:	25/07/1990	
ESTIGYN (Suspected)	Reas	on:			
	20.0 Microgram	Daily			
3atch:	Started:		Stopped:		CONTIN
PROVERA (Suspected)	Reas	on:			
	10.0 Milligram	Daily			
3atch:	Started:		Stopped:		CONTIN
ALLEGRON (Suspected)	Reas	on:	Depression		
	50.0 Milligram	Daily			
Зatch:	Started:		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	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:



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: 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 Detai

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

Medicine Details:

NORTAB (Interaction)

Reason: Depression

25.0 Milligram Daily

3atch: **3tarted**: 22/08/1990 **3topped**: 01/10/1991

NORTAB (Interaction) Reason: Depression

75.0 Milligram Daily

3atch: 3tarted: 04/09/1990 3topped:

NORTAB (Interaction) Reason: Depression

3atch: 3tarted: 05/10/1990 **3topped:**

PROZAC (Interaction) Reason: Depression

Capsule 20.0 Milligram Daily Oral

3atch: **3tarted**: 23/10/1990 **3topped**: 28/03/1991

100.0 Milligram

Laboratory Investigations:

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

Daily

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 Detai

Preferred Term	Severity	Report Description	Treatment
Tinnitus			

Medicine Details:

 NORTAB (Suspected)
 Reason:
 Anxiety neurosis

 0.0
 3atch:
 \$tarted:
 01/09/1989
 \$topped:
 28/12/1989

 NORTAB (Suspected)
 Reason:
 Anxiety neurosis

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/04/1992
 3topped:
 28/08/1992

Laboratory Investigations:

Date	Туре	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 Run 19/07/200 03:57PN Database: pusime ADRS004 Page 5 of 64



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: 82379 Seq: 1 Gender: F

 Reported:
 19/01/1993
 Weight:

 Hospitalisation:
 Age:

 Onset Date:
 04/01/1993
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration			
Neutropenia			

Medicine Details:

COGENTIN (Other drug)		Reason:				
	500.0 Microgram	Daily				
3atch:	Started: 18/07/1992		Stopped:		CONTIN	
STELAZINE (Suspected)		Reason:	Depression			
	40.0 Milligram	Daily				
3atch:	Started: 24/06/1992		Stopped:	05/01/1993		
NORTAB (Suspected)		Reason:				
	25.0 Milligram	Daily				
3atch:	Started: 22/12/1992		Stopped:	05/01/1993		

Laboratory Investigations:

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

Additional Information:



Report Detail

Case Number: 82643

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Seq: 1

Reported: 03/02/1993 Hospitalisation: Onset Date: Outcome: Recovered		Weight: Age: 55Y DOB: Causality: Causality pos			
Reaction Detai Preferred Term	Severity	Report Description	Treatment		
Dry mouth	Coverity	Teport Description	Treatment		
Dysphagia					
Mouth ulceration					
Medicine Details:					
NORTAB (Suspected)		Reason:			
3atch:	0.0 Started:	Stopped:			
Laboratory Investigatio	ne:				
Date Type	Range Date Tested	Result	Details		
Additional Information:					
eport Run 19/07/200 03:57PN	Database: pusime	ADRS004	Page 7 of 64		



Report Detail

Case Number: 84422

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

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

Seq: 1

Reported: 04/05/1993		Weight:				
spitalisation: Admitted to ho	spital	Age : 58				
Onset Date: 13/06/1992			DOB: 31/08/1933			
Outcome: Recovered		Causality: Causality probable				
action Detai			1			
Preferred Term	Severity	Report Description	Treatment			
zziness						
ushing						
yperhidrosis						
upraventricular tachycardia						
ledicine Details: NORTRIPTYLINE HYDROCHLORIDE	- (Suspected)	₹eason:				
TORTRI TTEME TITOROGILORIDE	0.0	(ed30ii.				
3atch:	Started:	Stopped:				
abaratary Investigation	•					
aboratory Investigations Date Type	Range Date Tested	Result	Details			
1,700	Date rected	rtooun	Botalio			
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 Detai

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

Medicine Details:

PETHIDINE HYDROCHLORIDE (In	teraction)	Reason:	Pain	
Injection	225.0 M	lilligram Tota	I	Intramuscular
3atch:	3tarted: 14/06	/1992	Stopped:	15/06/1992
NORTAB (Interaction)		₹eason:	Depression	
Tablet	100.0 M	lilligram Daily	,	Oral
3atch:	3tarted: 01/01	/1992	}topped:	21/06/1992
AURORIX (Other drug)		₹eason:	Depression	
	6.0 D	ose Unspecified Daily	,	
3atch:	3tarted: 20/05	/1993	Stopped:	
LITHICARB (Other drug)		₹eason:		
	500.0 M	lilligram Daily	,	
3atch:	3tarted: 01/06	/1993	Stopped:	

Laboratory Investigations:

	<u> </u>				
Date	Туре	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.

Report Run 19/07/200 03:57PN Database: pusime ADRS004 Page 9 of 64



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

Report D)etail					
Case Nun	mber: 88300	Seq: 1			Ge	nder: F
Repo	orted: 04/10/199	3			We	eight:
łospitalisa	ation:					Age: 73Y
Onset	Date:					DOB:
	ome: Unknown				Caus	ality: Causality possible
eaction		- 1				
	referred Term	Sever	ity	Repo	t Description	Treatment
Drug level Malaise	increased					
	e Details:	DE (Interaction)		Reas		
3ate	ch:	Starte	20.0 Milli	gram	Daily Stopped:	
	YLINE HYDROCHLO			Reas		
		•	100.0 Milli	gram	Daily	
3ate	ch:	Starte	ed:		Stopped:	2W
	ory Investigat					
Date	Туре	Range [Date Tested	Result		Details
	Serum drug level				after two months of taking patient's serum drug level	rtriptyline showed a level of 470 ug/l. 50mg of nortriptyline nightly the was 117 ug/l.
Addition	al Informatio	n:				



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

Re	po	rt	D	et	ai	
----	----	----	---	----	----	--

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 Detai

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

 NORTRIPTYLINE HYDROCHLORIDE (Suspected)
 Reason:
 Depression

 50.0
 Milligram
 Daily

 3atch:
 3tarted:
 09/08/1993
 3topped:
 30/08/1993

FLUOXETINE HYDROCHLORIDE (Suspected) Reason: Depression

 Tablet
 20.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/04/1992
 3topped:
 30/08/1993

Laboratory Investigations:

Date	Туре	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	t Detail
--------	----------

 Case Number:
 92023
 Seq:
 1
 Gender:
 M

 Reported:
 05/04/1994
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion		Nocturnal myoclonic jerks	

Medicine Details:

ALLEGRON (Suspected) Reason: Depression

 Oral application
 75.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 15/09/1993
 3topped:
 10/03/1994

Laboratory Investigations:

Date	Туре	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:
 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 Detai

todotion Dotal	ā		
Preferred Term	Severity	Report Description	Treatment
Anxiety			
Delirium			
Depersonalisation			
Hyperventilation			
Malaise			

Medicine Details:

ALPRAZOLAM (Other drug)		Reason:	Anxiety neuro	osis
Tablet	100.0 Milligram	Daily		Oral
3atch:	Started: 08/08/1994		Stopped:	29/08/1994
AROPAX (Suspected)		Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
3atch:	Started: 29/08/1994		Stopped:	29/08/1994
NORTRIPTYLINE HYDROCHLORIE	DE (Suspected)	Reason:	Depression	
Oral application	100.0 Milligram	Daily		Oral
3atch:	Started: 08/08/1994		Stopped:	29/08/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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:
 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 Detai

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

 ISOPTIN (Suspected)
 Reason: Essential benign hypertension

 120.0 Milligram Daily

 3atch:
 3tarted: 26/03/1991
 3topped:

ALLEGRON (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 01/01/1986 3topped:

Laboratory Investigations:

Date	Туре	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 Reported: 18/01/1995 lospitalisation: Onset Date: Outcome: Unknown				Gender: F Weight: Age: DOB: Causality: Causality possible				
<u>eaction Detai</u>		<u> </u>	<u> </u>				<u> </u>	
Preferre		Seve	erity	Repor	t Descriptio	n		Treatment
Orthostatic hypot	tension							
Medicine Det		ADINE (Suspecte	d)	2020	00.			
NORTRIPTYLINE I	HYDROCHLO	ORIDE (Suspecte		Reas				
3atch:		3tar	25.0 Milliq ted: 19/01/19		Daily 3to	pped:	02/02/199	4
NORTRIPTYLINE I	HYDROCHLO			Reas		-		
			75.0 Millio		Daily			
3atch:		3tar	ted: 03/02/19	994	3to	pped:	14/02/199	4
_aboratory In	vestigati	ions: Range	Date Tested	Result			Deta	ails
					<u> </u>			
Additional Inf	formation	n:						



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 Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

ALLEGRON (Suspected) Reason: Depression

0.0

3atch: 3tarted: 01/11/1994 **3topped:** 28/07/1995

ZOLOFT (Suspected) Reason: Depression

 Tablet
 3.0 Dose Unspecified Daily
 Oral

 3atch:
 Started:
 01/11/1994
 Stopped:
 28/07/1995

Laboratory Investigations:

Date	Туре	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 Run 19/07/200 03:57PN Database: pusime ADRS004 Page 16 of 64



Report Detail

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

ed: 07/02/1996 on: te: ne: Unknown	-	1		We	nder: F eight: Age: DOB: sality: Causality possible		
	Sev	verity	Repor	t Description	Treatment		
		. Only		· · · · · · · · · · · · · · · · · · ·			
Details:							
spected)			₹eas	on: Depression			
	St			Stopped:			
 pected)		artou.	Reas				
•		0.0					
	3t	arted:	Stopped:				
NE HYDROCHLOR	IDE (Suspec						
			Villigram				
		artou.		лоррец.			
· Investigatio	ons:						
Туре	Range	Date Teste	ed Result		Details		
	te: ne: Unknown stai erred Term Details: spected) NE HYDROCHLOR	de: ne: Unknown stai erred Term Seven Details: spected) Stai Details: Spected Spect	Details: Spected) Octails: Spected) Octails: Spected) Octails: Spected) Octails: Spected) Octails: Started: Started: Started: Started: Started: Started:	te: ne: Unknown stati erred Term Severity Report Details: spected) Started: NE HYDROCHLORIDE (Suspected) Started: 1	te: ne: Unknown Cause Itali Perred Term Severity Report Description Details: Spected) Reason: Depression 0.0 3tarted: 3topped: Dected) Reason: 0.0 3tarted: 3topped: NE HYDROCHLORIDE (Suspected) Reason: 25.0 Milligram Daily 3tarted: 3topped:		



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:
 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 Detai

Preferred Term	Severity	Report Description	Treatment
Anaemia			
Neutropenia	Severe		

Medicine Details:

PANADEINE FORTE (Other drug)		Reas	on:	
		1.0 Dose Unspecified	As necessary	
3atch:	Started:	01/02/1996	Stopped:	CONTIN
ENDONE (Other drug)		Reas	on:	
		1.0 Dose Unspecified	As necessary	
3atch:	Started:	01/01/1996	Stopped:	CONTIN
QUINIDINE BISULPHATE (Other drug)		Reas	on:	
		0.0	As necessary	
3atch:	Started:	01/01/1996	Stopped:	CONTIN
FRAGMIN (Other drug)		Reas	on:	
		5.0 Thousand Internat	Daily	
3atch:	Started:	01/01/1996	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	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 Run 19/07/200 03:57PN Database: pusime ADRS004 Page 18 of 64



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:
 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 Detai

Medicine Details:

Micaronic Details.				
METAMUCIL (Other drug)		Reason:		
	1.0 Dose Unspe	ecified Daily		
3atch:	Started: 01/01/1996		Stopped:	CONTIN
NORTRIPTYLINE HYDROCHLORIDE (Su	spected)	Reason:	Pain	
Tablet	10.0 Milligram	Daily		Oral
Зatch:	Started: 08/02/1996		Stopped:	26/02/1996
CARBAMAZEPINE (Suspected)		Reason:	Pain	
Tablet	200.0 Milligram	Daily		Oral
3atch:	Started: 12/02/1996		Stopped:	27/02/1996

Laboratory Investigations:

Date	Туре	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 Run 19/07/200 03:57PN Database: pusime ADRS004 Page 19 of 64



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 Gender: F
Reported: 04/07/1996 Weight:
Hospitalisation: Age: 79

Onset Date: DOB: 27/07/1916

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

SEREPAX (Other drug)		Reason:	Specific disorders of sleep
	30.0 Milligram	Daily	,
Зatch:	Started: 27/05/1996		Stopped:
SORBITOL (Other drug)		Reason:	Constipation
	30.0 Millilitre	Daily	,
3atch:	Started: 03/06/1996		Stopped:
CANESTEN (Suspected)		Reason:	Moniliasis
Ointment	0.0		Topical
3atch:	Started: 28/05/1996		Stopped: 05/06/1996
TAMOXIFEN CITRATE (Suspected)		Reason:	Malignant neoplasm of breast
	20.0 Milligram	Daily	,
Зatch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs



Report Detail

Case Number: 109716

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

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

Seq: 1

Reported : 04/07/1996			Weight:		
ospitalisation:			Age:	79	
Onset Date:			DOB:	27/07/1916	
Outcome: Not yet recovered			Causality:	Causality possi	ble
action Detai					
ledicine Details:					
NORTRIPTYLINE HYDROCHLORIDE (Su	spected)	Reason: Depression	on		
	20.0 Milligram	Daily			
Batch:	Started:	Stoppe	ed:		
COLOXYL WITH SENNA (Suspected)		Reason:			
	2.0 Dose Unspe	cified Daily			
3atch:	Started: 24/05/1996	Stoppe	ed: 12/06/1996		
-		· · ·			
aboratory Investigations:					
aboratory Investigations:					
dditional Information:					
ee original report for other drugs					
ort Run 19/07/200 03:57PN Databa	ise: pusime	ADRS004		Page 21	of 64



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

Report Detai						
Case Number: Reported: ospitalisation: Onset Date:	02/09/1996		1		Weig A	der: M ght: .ge: 11Y OB:
Outcome:					Causa	lity: Causality possible
eaction Detai		0		D	4 December 1999	Taratarant
Preferred Convulsion	d Ferm	Seve		Repor ic seizure.	t Description	Treatment
Medicine Deta NORTRIPTYLINE H		RIDE (Suspecte	d) 40.0 Mill	Reas ligram	on: Daily	
_aboratory In			D. T. ()	I 5 "	T	
Date	Туре	Range	Date Tested	Result		Details



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:
 Weight:

Hospitalisation: Age: 29Y

Onset Date: 26/11/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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	d)		Reason:		
Injection	100.0	Milligram	1 time	Intramuscular	
3atch:	Started:		:	topped:	
FENTANYL CITRATE (Suspected)			Reason:		
Injection	100.0	Microgram	1 time	Epidural	
Batch:	Started:		:	topped:	
XYLOCAINE (Suspected)			Reason:		
XYLOCAINE (Suspected)	10.0	Millilitre	Reason:		
XYLOCAINE (Suspected) 3atch:	10.0 Started:	Millilitre	1 time	itopped:	
	Started:	Millilitre	1 time	itopped:	
Satch:	Started:	Millilitre Millilitre	1 time	topped: Epidural	

Laboratory Investigations:

Date	Туре	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

Report Run 19/07/200 03:57PN Database: pusime ADRS004 Page 23 of 64



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 S	eq: 1				Gender:	F
Reported:	18/12/1996	-				Weight:	
Hospitalisation:						Age:	29Y
Onset Date:	26/11/1996					DOB:	
Outcome:	Recovered					Causality:	Causality possible
Reaction Detai							
Medicine Deta	ils:						
PROZAC (Suspecte	ed)			Reas			
			0 Milligram		Daily		
3atch:	VDDOCHI OBIDE (S	Started:		L TERM		Stopped:	
NORTRIPTTLINE	YDROCHLORIDE (Sus		0 Milligram	Reas	Daily		
3atch:		Started:	o wiiiigi ai ii	L TERM	Dully	Stopped:	
L							
Laboratory Inv	vestigations:						

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 Run 19/07/200 03:57PN Database: pusime ADRS004 Page 24 of 64



Report Detail

Case Number: 116647

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Seq: 1

Reported: 09/04/19	197	_						
ospitalisation: Onset Date: 02/03/19	107			Age: 77Y DOB:				
Outcome: Unknown			Cau	usality: Causality possible				
action Detai	1		Oat	isanty. Causanty possible				
Preferred Term	Severity	Repo	rt Description	Treatment				
sthenia			•					
oordination abnormal								
ry mouth								
eadache								
omnolence								
sual disturbance								
edicine Details:								
/ALIUM (Other drug)		Reas	son:					
	1.0	Milligram	Daily					
3atch:	Started:		Stopped:					
OHYPNOL (Other drug)		Reas	son:					
	0.5	Milligram	Daily					
3atch:	Started:		Stopped:					
LLEGRON (Suspected)		Reas						
Tablet		Milligram	,	Oral				
3atch:	Started: 11		Stopped:					
VENTYL (Suspected)		Reas						
Oral application		Milligram	,	Oral				
3atch:	Started: 11	/02/1997	Stopped:					
aboratory Investiga		T	T					
Date Type	Range Date Tes	sted Result		Details				
dditional Informatio	on:							
rt Run 19/07/200 03:57P	PN Database: pusime		ADRS004	Page 25 of 64				



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 Detai

104011011 20141		-	
Preferred Term	Severity	Report Description	Treatment
Delirium		Anticholinergic delirium	Nortriptyline ceased
Confusional state			

Medicine Details:

MAXOLON (Other drug)		Reason:		
Oral application	30.0 Milligram	Daily	Oral	
3atch:	Started:		Stopped:	CONTIN
VENTOLIN (Other drug)		Reason:	Otr respiratory systm diseases	3
Inhalation	20.0 Milligram	Daily	Inhalation	
3atch:	Started:		Stopped:	CONTIN
ATROVENT (Other drug)		Reason:	Otr respiratory systm diseases	3
Inhalation	2.0 Milligram	Daily	Inhalation	
3atch:	Started:		Stopped:	CONTIN
IMDUR (Other drug)		Reason:	Chron isch heart dis no hyper	
	60.0 Milligram	Daily		

Laboratory Investigations:

Date	Туре	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: 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 Detai

Medicine Details:

PRINIVIL (Other drug)		Reason:		
	2.5 Milligram	Daily		
Зatch:	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		
3atch:	Started:		Stopped:	CONTIN
PULMICORT (Other drug)		Reason:		
Inhalation	400.0 Microgram	Daily	Inhala	ation
Batch:	Started:		Stopped:	CONTIN

Laboratory Investigations:

Additional Information:



Report Detail

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

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 proba	ble
Reaction Detai							
Medicine Deta	aile:						
	HYDROCHLORIDE (Si	uspected)	Reason:	Depression			
	•	100.0 Milligram	Daily	·			
3atch:		Started: 25/10/1996	•	Stopped:			
Laboratory In	voetigatione:						
Laboratory in	vestigations.						
Additional Inf	ormation:						

Report Run 19/07/200 03:57PN Database: pusime ADRS004 Page 28 of 64



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:122419Seq:1Gender:UReported:18/11/1997Weight:Hospitalisation:Age:

Onset Date: 31/07/1997

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Detai

teaction Detai			
Preferred Term	Severity	Report Description	Treatment
Rash			
Vomiting			

Medicine Details:

AVENTYL (Suspected) Reason:

0.0

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Causality: Causality possible

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

Re	por	t D	etail
----	-----	-----	-------

Case Number: 122504 Seq: 1 Gender: F
Reported: 18/11/1997 Weight:
Hospitalisation: Age: 42Y

Onset Date: DOB:

Outcome: Not yet recovered

Reaction Detai

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

Medicine Details:

AVENTYL (Suspected)

25.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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 Detai

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

Medicine Details:

ALLEGRON (Suspected)

Oral application

3atch:

Started: 01/09/1997

Reason:
Daily
Oral
Stopped:

Laboratory Investigations:

Date	Туре	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 Det	ail					
Hospitalisatio	d: 15/12/199 n: Admitted	to hospital			DOB	: : 61Y
Reaction De	tai	_			_	
	rred Term	Severity	Repor	t Description		Treatment
Atrial fibrillation Atrioventricula Hypertension Tachycardia					Noi	triptyline discontinued
Medicine D						
ZOLOFT (Susp	ected)		Reas	•		
Tablet			0 Milligram	Daily	Oral	
3atch:	NE HYDROCHI (Started: ORIDE (Suspected)	Reas	on: Depression		
	plication		0 Milligram	Daily	Oral	
3atch:	piiodiioii	Started:	g. a	Stopped		
Laboratory Date	Investigat	ions: Range Date To	ested Result		Det	ails
2410	.,,,,,	range Bate I	- Troour		Det	
Additional	Informatio	n:				



Report Detail

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

Case Number:	126917	Seq: 1				Gender:	M	
Reported:	24/04/1998	-				Weight:		
lospitalisation:						Age:	41	
Onset Date:						DOB:	29/12/1956	
Outcome:	Not yet recove	ered		Causalit			Causality poss	ible
eaction Deta	n i							
	ed Term	Severity		Repo	rt Description		Treatment	
achycardia			Persi	stent tachyc	ardia			
ory mouth innitus								
ledicine Det				Reas	son: Depres	sion		
Tablet	. ,	10	O.O Milli		Daily	Oral		
3atch:		Started:			Stop	ped:		
aboratory l	nvestigation	s:						
Date			Tested	Result		Deta	nils	
dditional In	formation:							
ort Run 19/07/20	00 03:58PN D	atabase: pusime		,	ADRS004		Page 33	of 64



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:
 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 Detai

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

Medicine Details:

Medicine Details.			
NORVASC (Suspected)		Reason: Essential ben	ign hypertension
Tablet	5.0 Milligram	Daily	Oral
Зatch:	Started: 01/01/1998	Stopped:	31/01/1998
ALLEGRON (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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.

Report Run 19/07/200 03:58PN Database: pusime ADRS004 Page 34 of 64



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 Detai

Preferred Term	Severity	Report Description	Treatment
Nightmare			

Medicine Details:

ALLEGRON (Suspected) Reason: Depression

Oral application 75.0 Milligram Daily Oral

3atch: **3tarted**: 01/01/1997 **3topped**: CONTIN

Laboratory Investigations:

Date	Туре	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 Run 19/07/200 03:58PN Database: pusime ADRS004 Page 35 of 64



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
 Gender:
 F

 Reported:
 09/03/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 83Y
Onset Date: 13/02/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZANTAC (Other drug)	Reason:					
	300.0	Milligram	Daily			
Зatch:	Started:			Stopped:		
CARTIA (Other drug)	Reason:					
	100.0	Milligram	Daily			
Зatch:	Started:			Stopped:		
MODURETIC (Other drug)	Reason:					
	1.0 Dose Unspecified Daily					
3atch:	Started:			Stopped:		
NORVASC (Suspected)	Reason:					
	10.0	Milligram	Daily			
3atch:	Started:			Stopped:	13/02/1999	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: #1) 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 D	etai
----------	------

 Case Number:
 137106
 Seq: 1
 Gender:
 F

 Reported:
 09/03/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 83Y
Onset Date: 13/02/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

Medicine Details.					
ALLEGRON (Suspected)	Reason:				
	50.0 Milligram	Daily			
3atch:	Started:	Stopped	: 15/02/1999		
BETALOC (Suspected)		Reason:			
	150.0 Milligram	Daily			
3atch:	Started:	Stopped	:		

Laboratory Investigations:

Additional Information:

Sequelae: #1) fibula. patient history: ht, ihd, hiatus hernia, r) cea, l) carotid sterosis & direrticulosis.

Report Run 19/07/200 03:58PN Database: pusime ADRS004 Page 37 of 64



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 Detai

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

Medicine Details:

NORTRIPTYLINE HYDROCHLORIDE (Suspected) Reason: Depression

0.0

3atch: 3tarted: 3topped: 28/06/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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: 151804 Seq: 1 Gender: M

Reported: 17/04/2000 Weight:
Hospitalisation: Age:
Onset Date: 14/03/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Dotal		<u> -</u>	
Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous		Blisters on the tongue.	
Tongue oedema			Allegron discontinued.

Medicine Details:

PREDNISONE (Suspected)		Reason:	Rash	
Tablet	0.0			Oral
3atch:	Started:		Stopped:	
ALLEGRON (Suspected)		Reason:	Depression	
Tablet	12.5 Milligram	Daily		Oral
3atch:	Started: 14/03/2000		Stopped:	14/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Shortly after taking half an allegron tablet, reactions occurred.



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:
 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 Detai

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

Medicine Details:

MODURETIC (Suspected)	Reason:			
Oral application	1.0 Dose Unspecified	d Daily	Oral	
3atch:	Started : 25/04/2000	Stopped:	02/05/2000	
NICOTINIC ACID (Suspected)	₹ea	ison:		
	1.0 Dose Unspecified	d Daily		
3atch:	Started:	Stopped:	02/05/2000	
ALLEGRON (Suspected)	₹ea	ison:		
	20.0 Milligram	Daily		
Зatch:	Started:	Stopped:	02/05/2000	
LPV (Suspected)	₹ea	ison:		
Oral application	2.0 Gram	Daily	Oral	
3atch:	Started: 25/04/2000	Stopped:	02/05/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run 19/07/200 03:58PN Database: pusime ADRS004 Page 40 of 64



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
 Gender:
 F

 Reported:
 24/08/2000
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 27/06/2000
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hallucination			Diazepam and cyproheptadine.

Medicine Details:

mountaine Detailer				
PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	Depression	
	0.0			
3atch:	Started:		Stopped:	27/06/2000
NORTRIPTYLINE HYDROCHLORIDE (Suspected)		Reason:	Depression	
	0.0			
3atch:	Started:		Stopped:	27/06/2000

Laboratory Investigations:

Date	Туре	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 Detai

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

Medicine Details:

ALLEGRON (Suspected) Reason: Depression

75.0 Milligram Daily

3atch: 3tarted: 01/11/2000 **3topped:** 08/11/2000

Laboratory Investigations:

Date	Туре	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 Gender: F

 Reported:
 02/04/2001
 Weight:
 81.00

 Hospitalisation:
 Age:
 55Y

Onset Date: 02/03/2001 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

ALLEGRON (Suspected) Reason:

100.0 Milligram Daily

3atch: 3tarted: 01/10/2000 3topped: 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.

Report Run 19/07/200 03:58PN Database: pusime ADRS004 Page 43 of 64



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 Detai

todotion Botal		E	<u> - </u>
Preferred Term	Severity	Report Description	Treatment
Dysgeusia		Strange taste	
Convulsion			Zyban ceased. patient

Medicine Details:

ZYBAN SR (Interaction)		Reason:	Depression		
	300.0 Milligram	Daily			
3atch:	3tarted: 01/03/2001		Stopped:	26/04/2001	
ALLEGRON (Interaction)		Reason:			
	20.0 Milligram	Daily			
3atch:	Started:		Stopped:		
LITHIUM CARBONATE (Other drug)		Reason:			
LITHIUM CARBONATE (Other drug)	300.0 Milligram	Reason: Daily			
LITHIUM CARBONATE (Other drug) 3atch:	300.0 Milligram		Stopped:		
, 5,	· ·				
3atch:	· ·	Daily	Stopped:		

Laboratory Investigations:

Date	Туре	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 Run 19/07/200 03:58PN Database: pusime ADRS004 Page 44 of 64



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 Detai

Medicine Details:

ZYBAN SR (Interaction)		Reason:	Depression	
	300.0 Milligram	Daily		
3atch:	3tarted: 01/03/2001		Stopped:	26/04/2001
ALLEGRON (Interaction)		Reason:		
	20.0 Milligram	Daily		
Зatch:	Started:		3topped:	
LITHIUM CARBONATE (Other drug)		Reason:		
	300.0 Milligram	Daily		
3atch:	Started:		Stopped:	
THYROXINE SODIUM (Other drug)		Reason:		
	100.0 Microgram	Daily		
	•			

Laboratory Investigations:

Date	Туре	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.

Report Run 19/07/200 03:58PN Database: pusime ADRS004 Page 45 of 64



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 Detai

touction Botal			
Preferred Term	Severity	Report Description	Treatment
Hypotension			
Orthostatic hypotension Tachycardia			

Medicine Details:

ALLEGRON (Suspected) Reason:

50.0 Milligram Daily

3atch: 3tarted: 03/03/2001 3topped: 29/04/2001

Laboratory Investigations:

Date	Туре	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 Detai

104011011 20141		-	
Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Patient presented with fall.	
Dyskinesia			Ceased allergron and commenced pantoprazole.

Medicine Details:

Medicine Details.						
ALLEGRON (Suspected)			Reason:	Depression		
Tablet	200.0	Milligram	Daily	Ora	I	
3atch:	Started:	L TI	ERM	Stopped:		
RANI 2 (Suspected)			Reason:	Other diseases of e	sophagus	
Tablet	300.0	Milligram	Daily	Ora	I	
3atch:	Started:	L TI	ERM	Stopped:		

Laboratory Investigations:

Date	Туре	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 Detai

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

Medicine Details:

KAPANOL (Suspected)		Reason:	Pain	
Capsule	140.0 Milligram	n Daily	Oral	
Зatch:	Started:	L TERM	Stopped:	CONTIN
NORTRIPTYLINE HYDROCHLORIDE (Susp	ected)	Reason:	Pain	
Tablet	75.0 Milligram	n Daily	Oral	
3atch:	Started: 16/08/2001		Stopped:	CONTIN
GABAPENTIN (Suspected)		Reason:	Pain	
Capsule	800.0 Milligram	n Daily	Oral	
Зatch:	Started: 24/08/2001		Stopped:	CONTIN
RANITIDINE (Suspected)		Reason:	Other diseases of esopha	ngus
Tablet	300.0 Milligram	n Daily	Oral	
Зatch:	Started:	L TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run 19/07/200 03:58PN Database: pusime ADRS004 Page 48 of 64



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

 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 Detai

Medicine Details:

CLEXANE (Suspected)		Reason:	Phleb&thrombophleb lowr 6	extrem
Injection	90.0 Milligram	Daily	Intravenous	
3atch:	Started: 29/08/2001		Stopped:	CONTIN
DEVAMETHACONE (Cuprocted)				
DEXAMETHASONE (Suspected)		Reason:		
Oral application	4.0 Milligram	Reason: Daily	Oral	

Laboratory Investigations:

Additional Information:

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

Report Run 19/07/200 03:58PN Database: pusime ADRS004 Page 49 of 64



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 Detai

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

Medicine Details:

MAXOLON (Other drug)		Reason:	Nausea and v	omiting
Oral application	0.0			Oral
3atch:	Started:		Stopped:	23/09/2001
DEXAMETHASONE (Other drug)		Reason:		
Oral application	0.0			Oral
3atch:	Started:		Stopped:	23/09/2001
COLOXYL WITH SENNA (Other drug)		Reason:	Constipation	
Oral application	0.0			Oral
3atch:	Started:		Stopped:	23/09/2001
FLAGYL (Other drug)		Reason:		
Cream	0.0			Topical
3atch:	Started:		Stopped:	23/09/2001

Laboratory Investigations:

Date	Туре	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 Detai

Medicine Details:

SILVER SULPHADIAZINE (Other drug	g)		Reason:		
		0.0			
Batch:	Started:			Stopped:	
KAPANOL (Other drug)			Reason:	Pain	
Oral application		0.0			Oral
3atch:	Started:			Stopped:	23/09/2001
NORTRIPTYLINE HYDROCHLORIDE	(Suspected)		Reason:	Pain	
Oral application		0.0			Oral
3atch:	Started:	16/08/2001		Stopped:	23/09/2001
CLEXANE (Suspected)			Reason:		
Injection		0.0			Subcutaneous
3atch:	Started:	28/08/2001		Stopped:	23/09/2001

Laboratory Investigations:

Additional Information:

Patient with metastatic breast cancer.



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

Case Number:	169221	Seq: 1			Gender:	F	
Reported:	15/10/2001				Weight:		
Hospitalisation:					Age:	60Y	
Onset Date:					DOB:		
	Unrelated death			C	ausality:	Causality poss	ible
Reaction Detai							
Medicine Deta	ails:						
NEURONTIN (Susp			Reason:	Pain			
Oral applica	ation	800.0 Milligram	Daily		Oral		
3atch:		3tarted: 01/08/2001		Stopped:	23/09/2001		
Laboratory In	vestigations:						
•	3						
Additional Inf	ormation:						
Patient with metast							
. Guone man motaot	5. 5451 64.1661.						
teport Run 19/07/200	03:58PN Data	base: pusime	ADRS00	04		Page 52	of 64
	JULIUS II Data	acc. pacino	, 1011000	• •		raye 32	UI U 1



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

Date Type	Range	Date Tested	Result		Details
Laboratory Investigatio					
3atch:	€ta	25.0 Milli irted:	gram	Daily Stopped:	
Medicine Details: ALLEGRON (Suspected)			Reas	on:	
Gingival bleeding	<u> </u>				
Preferred Term	Sev	erity	Repor	t Description	Treatment
Outcome: Recovered eaction Detai				Caus	sality: Causality probable
					DOB : 11/07/1956
Onset Date: 01/05/2002					Age: 45
Reported: 05/08/2002 Hospitalisation: Onset Date: 01/05/2002				VV	eight: 59.00



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:
 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 Detai

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

Medicine Details:

TRAMAL SR (Interaction)		Reason:	
Tablet	200.0 Milligram	As necessary	Oral
3atch:	Started:	Stopped:	
ALLEGRON (Interaction)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	
HYPERICUM-ST JOHN'S WORT (Other dr	ug)	Reason: Depression	
		Daily	Oral
3atch:	Started:	Stopped:	
		• •	
CELEBREX (Other drug)		Reason:	
CELEBREX (Other drug) Capsule	200.0 Milligram	Reason:	Oral

Laboratory Investigations:

Date	Туре	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.



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: 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 Detai

Caution Botal							
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	
3atch:	Started: 09/08/2002		Stopped:	
ZOCOR (Suspected)		Reason:	Othr&unspec metabolic diseases	
ZOCOR (Suspected) Tablet	10.0 Milligram	Reason: Daily	Othr&unspec metabolic diseases Oral	

Laboratory Investigations:

Date	Туре	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 Detai

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

Medicine Details:

Medicine Details:			
ROCALTROL (Suspected)		Reason: Osteoporosis	
3atch:	Started:	Stopped:	
ALLEGRON (Suspected)		Reason: Anxiety neurosis	
Tablet	75.0 Milligram	Daily Oral	
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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.

Report Run 19/07/200 03:58PN Database: pusime ADRS004 Page 56 of 64



Hospitalisation:

Case Number: 197475

Reported: 20/05/2004

Onset Date: 11/02/2004

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Age: 28

DOB: 16/06/1975

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

Seq: 1

Outcome: Unknown		Causality: Causality possible			
Preferred Term	Seve	rity	Report	Description	Treatment
Attention deficit/hyperactivity disc	disc Attention deficit disorder, drowsiness, light headedness, fine tremor and pins & needles in extremeties.				
Dizziness					
Paraesthesia					
Somnolence					
Ггетог					
Medicine Details:					
ZOTON (Other drug)			Reaso	1:	
3atch:	Star	ted:		Stopped:	
ALLEGRON (Suspected)			Reaso	1:	
				Daily	
3atch:	Start	ted:		Stopped:	Continuing
aboratory Investigations					
_aboratory Investigations Date Type R		Date Tested	Result	Do	etails
24.0	ango	Bato Footoa	rtooun		Stano
Additional Information:					
oort Run 19/07/200 03:58PN Dat	abase: pus	ime	AD	RS004	Page 57 of 64



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

Report D)etail
----------	--------

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 Detai

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Agitation		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

 3atch:
 3tarted:
 09/03/2004
 3topped:
 20/03/2004

Laboratory Investigations:

Date	Туре	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
 Gender:
 F

 Reported:
 11/08/2005
 Weight:
 0.00

Hospitalisation: Hospitalisation prolonged **Age**: 49

Onset Date: 01/01/2005 DOB: 17/06/1955
Outcome: Unknown Causality: Causality possible

Reaction Detai

Cachon Detai			
Preferred Term	Severity	Report Description	Treatment
Encephalopathy	prolonged inpatient		Patient was transferred to Royal Melbourne Hospital
Paranoia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Int	Reason:				
Capsule	225.0	Milligram			Oral
3atch:	Started:		Stopped:		
NORTRIPTYLINE HYDROCHLORIDE (Interaction)			Reason:		
Tablet	175.0	Milligram			Oral
3atch:	Started:			Stopped:	
GABAPENTIN (Other drug)			Reason:		
GABAPENTIN (Other drug)	1200.0	Milligram	Reason:		Oral
GABAPENTIN (Other drug) 3atch:	1200.0 Started:	Milligram	Reason:	Stopped:	Oral
, ,	Started:	Milligram	Reason:	Stopped:	Oral
3atch:	Started: ner drug)	Milligram Milligram		Stopped:	Oral Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Case Number: 210578

Reported: 11/08/2005

Onset Date: 01/01/2005

Hospitalisation: Hospitalisation prolonged

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Age: 49

DOB: 17/06/1955

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

Seq: 1

Outcome: Unknown Causality: Causality action Detai					usality poss	ible	
icine Details:							
OTRIGINE (Other drug)			Reason:				
Tablet		Milligram			Oral		
3atch:	Started:			Stopped:			
AXONE (Other drug)			Reason:		0		
Injection	No mto al c		Daily	Manuard.	Subcutaneous		
3atch:	Started:		2	Stopped:			
HYSERGIDE MALEATE (Other drug		NATIO	Reason:		01		
Tablet		Milligram	Daily	Manuard.	Oral		
3atch:	Started:			Stopped:	13/01/2005		
ooratory Investigations:							
itional Information:							
un 19/07/200 03:58PN Datab	ase: pusime		ADRS004			Page 60	of G



Case Number: 214539

Reported: 04/01/2006

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

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

Seq: 1

ospitalisatio				Age: 46					
Onset Da	ne: Unknown			DOB: 09/09/1959					
action De				Causality: Causality possible					
	erred Term	Se ⁻	verity	Report D	escription	Treatment			
erotonin syr	ndrome		The p	patient develope					
kathisia			Synai	rome and sever					
F	Dodoilo.								
edicine [ANADEINE F	Jetails: FORTE (Other dru	g)		Reason:	:				
2-4-6-		•	tanta di		Mannada				
3atch: UROFEN (Ot			tarted:	}topped: Reason:					
3atch:		20	tarted:		Stopped:				
ALIUM (Othe			tarteu:	Reason:					
Zatah		>-	tarted:		Stopped:				
3atch: ORTRIPTYLI	INE HYDROCHLO			Reason:					
			,		Oral				
3atch:	:	31	tarted:	Stopped:					
boratory	y Investigat	ions:							
Date	Туре	Range	Date Tested	Result		Details			
dditional	Information	1:							
rt Run 19/0	7/200 03:58PN	Database: p	ousime	ADR	RS004	Page 61 of 64			



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 Reported: 04/01/2006 Hospitalisation: Onset Date: Outcome: Unknown Reaction Detai	Seq: 1		: 0.00
Medicine Details:			
Lexapro (Suspected)		Reason: Oral	
3atch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
3atch:	Started:	Stopped:	
Laboratory Investigations	:		
Additional Information:			

Report Run 19/07/200 03:58PN Database: pusime ADRS004 Page 62 of 64



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 Gender: F

Reported: 11/01/2006 Weight: 53.00 Hospitalisation: Admitted to hospital Age: 20

Onset Date: 09/11/2005 **DOB**: 30/03/1985

Outcome: Unknown Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
		experiencing a seizure.	EEG/for further investigation.

Medicine Details:

vieuicine Delans.					
LITHIUM CARBONATE (Other drug)	Reason:				
	1.0	Gram	Daily		
3atch:	Started:		STERM	Stopped:	
ALLEGRON (Suspected)			Reason:	Depression	
Tablet	75.0	Milligram	Daily		Oral
3atch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No history of alcohol misuse or befrile convulsions.



Case Number: 217242

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

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

Seq: 1

Hospitalisati	ted: 10/04/2006		Weight: 0.00		
Hospitalisation: Admitted to hospital			Age: 42Y		
Onset Date: 11/11/2005			DOB:		
	me: Recovered			Causa	lity: Causality possible
Reaction D		1			
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					
ALLEGRON (Suspected) Reason:					
			Milligram Daily		
3atch:		Started: Stopped: 0			0
	ry Investigations		seted Result	Γ	Details
Laborator Date		S: Range Date Te	ested Result		Details