

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
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 Case Number:
 187560
 Seq: 1
 Gender:
 M

 Reported:
 25/06/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 54

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Sleep disorder		Patient has noticed difference in the quality of his sleep. Patient described it as a "prolonged blackout", feels like he is "half-asleep", "half-awake" and has not had any dreams.	

Medicine Details:

Abilify (Suspected)		Reason:			
Tablet	15.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
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Additional Information:

Patient was also taking Cipramil and Eilim.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Ren	ort	Deta	ils:
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Case Number: 187879 Seq: 1 Gender: M

Reported: 27/06/2003 Weight: 90.00 Hospitalisation: Age: 36

Onset Date: 23/06/2003 **DOB**: 14/03/1967

Outcome: Recovered 24/06/2003 Causality: Causality probable

Reaction Details:

touction Details.			
Preferred Term	Severity	Report Description	Treatment
Condition aggravated		Increased psychotic Symptoms, tremor and feeling cold.	
Tremor		Increased psychotic Symptoms, tremor and feeling cold.	
Feeling cold		Increased psychotic Symptoms, tremor and feeling cold.	

Medicine Details:

Aripiprazole (Suspected)		Reason:	Schizophrenia	
Tablet	15.0 Milligram	Daily		Oral
Batch:	Started: 16/06/2003		Stopped:	23/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number:191364Seq: 1Gender: MReported:16/10/2003Weight: 0.00Hospitalisation:Age: 35

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

baotion Botanoi							
Preferred Term	Severity	Report Description	Treatment				
Dizziness			Felt faint while exercising with weights.				
Tachycardia			Felt faint while exercising with weights.				

Medicine Details:

Medicine Details.				
Abilify (Suspected)		Reason:	Schizophrenia	
	15.0 Milligram	Daily		Oral
Batch:	Started: 03/08/2003		Stopped:	15/09/2003
EDRONAX (Suspected)		Reason:	Depression	
Tablet	8.0 Milligram	Daily		
Batch:	Started: 21/07/2003		Stopped:	15/09/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
16/10/2003	Other data				

Additional Information:

Patient also taking Seroquel and Topamax.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number:192069Seq: 1Gender: MReported:11/11/2003Weight: 0.00Hospitalisation:Admitted to hospitalAge: 30

Onset Date: 07/10/2003 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		He was treated with subcutaneous low molecular weight heparin and recovered. He is currently on Warfarin.

Medicine Details:

Abilify (Suspected)		Reason: Schiz	ophrenia	
Tablet	30.0 Milligram	Daily	Oral	
Batch:	Started:	s	topped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Abilify started Oct 2003.

The patient is obese and a smoker. He has no other risk factors for DVT. There is no family history of hypercoaguable disorder. Other drugs used: Clozapine, Diazepam and Venlafaxine.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Numb	er: 192275	Seq: 1		G	ender:	F
Report	ed: 17/11/2003			W	eight:	0.00
ospitalisatio	on:				Age:	56
Onset Da	ate: 30/10/2003				DOB:	03/08/1947
Outcon	ne: Recovered			Cau	sality:	Causality probable
action De	etails:					
Pre	ferred Term	Severity	Report	Description		Treatment
Hypersensitiv	⁄ity		Hypersensitivity			
ip swelling						
Pruritus						
Rash papulai	<u>r </u>					
Medicine [Details:	(Other drug)	Reason			
FLUOXETINE	HYDROCHLORIDE		Reason Dose Unspecified Da			
Batch	n•	Started:	Dose Offspecified Da	Stopped:		
Abilify (Suspe		- Ctartour	Reason			
Tablet		45.0		•		
1 45101	•	15.0	i iviiiiigram Da	ily O	ral	
Batch		Started: 27	=	Stopped: 02		
Batch	ı: y Investigatio	Started: 27	=	•		
Batch	1:	Started: 27	7/10/2003	•		

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 192277 Seq: 1 Gender: F

Reported: 17/11/2003 Weight: 0.00 Hospitalisation: Age: 37

Onset Date: 12/09/2003 **DOB**: 08/07/1966

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation	Vomiting, headache, agitation and anxiety.	
Agitation	Caused or prolonged inpatient hospitalisation		
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected) Reason: Hallucinations

Tablet 15.0 Milligram Daily Oral

Batch: Started: 12/09/2003 Stopped: 12/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Within 1-2 hours after receiving her initial dose of Aripiprazole, 15 mg/day. Patient also administered: Edronax, Zyprexa.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	ort	Detail	ls:
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Case Number: 192277 Seq: 1 Gender: F

Reported: 17/11/2003 Weight: 0.00 Hospitalisation: Age: 37

Onset Date: 12/09/2003 **DOB**: 08/07/1966

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Headache	Caused or prolonged inpatient hospitalisation		

Medicine Details:

I	Abilify (Suspected)		Reason:	Hallucinations	
	Tablet	15.0 Milligram	Daily		Oral
	Batch:	Started: 12/09/2003		Stopped:	12/09/2003

Laboratory Investigations:

Additional Information:

Within 1-2 hours after receiving her initial dose of Aripiprazole, 15 mg/day. Patient also administered: Edronax, Zyprexa.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	oort	De	tai	s:
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 Case Number:
 192358
 Seq: 1
 Gender:
 F

 Reported:
 20/11/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 36

Onset Date: 07/11/2003 DOB: 04/03/1967

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	prolonged	Increased CK level, increased drug level, confused, deliriouss, light hyperreflexia, tachycardic.	
	Caused or prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

modific Botanoi		
CLOPINE (Interaction)		Reason: Unspecified schizophrenia
Tablet	400.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 07/11/2003
Abilify (Interaction)		Reason:
Tablet	15.0 Milligram	Daily Oral
Batch:	Started:	Stopped : 07/11/2003
VALIUM (Other drug)		Reason: Anxiety neurosis
Tablet	5.0 Milligram	As necessary Oral
Batch:	Started:	Stopped : 07/11/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:		
Case Number: 192358	Seq: 1	Gender: F

Reported: 20/11/2003 Weight: 0.00 Hospitalisation: Age: 36

Onset Date: 07/11/2003 **DOB**: 04/03/1967

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug interaction	Caused or prolonged inpatient hospitalisation		
Drug level increased	Caused or prolonged inpatient hospitalisation		
Hyperreflexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

modific Botanoi		
CLOPINE (Interaction)		Reason: Unspecified schizophrenia
Tablet	400.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 07/11/2003
Abilify (Interaction)		Reason:
Tablet	15.0 Milligram	Daily Oral
Batch:	Started:	Stopped : 07/11/2003
VALIUM (Other drug)		Reason: Anxiety neurosis
Tablet	5.0 Milligram	As necessary Oral
Batch:	Started:	Stopped : 07/11/2003

Laboratory Investigations:

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rei	port	Detai	ls:
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 Case Number:
 192358
 Seq: 1
 Gender:
 F

 Reported:
 20/11/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 36

Onset Date: 07/11/2003 **DOB:** 04/03/1967

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Interaction)		Reason: Unspecified schizophrenia
Tablet	400.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 07/11/2003
Abilify (Interaction)		Reason:
Tablet	15.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 07/11/2003
VALIUM (Other drug)		Reason: Anxiety neurosis
Tablet	5.0 Milligram	As necessary Oral
Batch:	Started:	Stopped: 07/11/2003

Laboratory Investigations:

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 192487
 Seq: 1
 Gender:
 M

 Reported:
 25/11/2003
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 50
Onset Date: 25/09/2003
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	prolonged inpatient	Hyponatraemia, paranoia, aggression, delusion, thinking abnormal, blood chloride, blood urea, blood creatinine all decreased.	
Aggression	Caused or prolonged inpatient hospitalisation		
Blood chloride decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)		Reason:	Schizophrenia	
Oral application	15.0 Milligram	Daily		Oral
Batch:	Started: 12/09/2003		Stopped:	05/10/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
25/11/2003	Chloride		08/10/2003	89 MMOL/L	
25/11/2003	Chloride		14/10/2003	88 MMOL/L	
25/11/2003	Creatinine		08/10/2003	58 MMOL/L	
25/11/2003	Creatinine		14/10/2003	70 MMOL/L	
25/11/2003	Potassium		08/10/2003	4.7 MMOL/L	
25/11/2003	Potassium		14/10/2003	4.6 MMOL/L	
25/11/2003	Sodium		08/10/2003	127 MMOL/L	

Additional Information:

Patient also administered: Zyprexa, Moducare, Largactil, Solian.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 192487
 Seq: 1
 Gender:
 M

 Reported:
 25/11/2003
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 50
Onset Date: 25/09/2003
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine decreased	Caused or prolonged inpatient hospitalisation		
Blood urea decreased	Caused or prolonged inpatient hospitalisation		
Delusion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)		Reason:	Schizophrenia	
Oral application	15.0 Milligram	Daily		Oral
Batch:	Started: 12/09/2003		Stopped:	05/10/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
25/11/2003	Sodium		14/10/2003	127 MMOL/L	
25/11/2003	Urea		08/10/2003	2.2 MMOL/L	
25/11/2003	Urea		14/10/2003	2.5 MMOL/L	

Additional Information:

Patient also administered: Zyprexa, Moducare, Largactil, Solian.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls	:
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Case Number:192487Seq: 1Gender: MReported:25/11/2003Weight: 0.00Hospitalisation:Admitted to hospitalAge: 50

Onset Date: 25/09/2003 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paranoia	Caused or prolonged inpatient hospitalisation		
Thinking abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)		Reason:	Schizophrenia	
Oral application	15.0 Milligram	Daily		Oral
Batch:	Started: 12/09/2003		Stopped:	05/10/2003

Laboratory Investigations:

Additional Information:

Patient also administered: Zyprexa, Moducare, Largactil, Solian.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 192881 Seq: 1 Gender: M

Reported: 05/12/2003 Weight: 80.00 Hospitalisation: Age: 31

Onset Date: 29/11/2003 DOB: 21/02/1972

Outcome: Recovered 30/11/2003 Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Amnesia		Gross amnesia and psychomotor slowing, leading to pushbike accident.	
Psychomotor skills impaired	Required Visit to Doctor		
Road traffic accident	Required Visit to Doctor		

Medicine Details:

Medicine Details.			
Abilify (Interaction)		Reason:	
Tablet	7.5 Milligram	Daily Oral	
Batch:	Started: 25/11/2003	Stopped: 30/11/2003	
STILNOX (Interaction)		Reason: Specific disorders of sleep	
Tablet	20.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Abilify slowing metabolism of Stilnox via cytochrome 450 344 and subsequent amnesia.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 193274 Seq: 1 Gender: F

Reported: 17/12/2003 Weight: 0.00 Hospitalisation: Age: 17

Onset Date: 05/12/2003 **DOB**: 15/01/1986

Outcome: Recovered 05/12/2003 Causality: Causality possible

Reaction Details:

teaction Details.				
Preferred Term	Severity	Report Description	Treatment	
Depressed level of consciousness		Consciousness impaired.	Required ICU admission, given Flumazenil 500mg iv with rapid response.	

Medicine Details:

SEROQUEL (Interaction)		Reason: Otr spec symp psychopathol nec	
Batch:	Started:	Stopped:	
MIDAZOLAM (Interaction)		Reason: Otr spec symp psychopathol nec	
Injection	10.0 Milligram	As necessary Intramuscular	
Batch:	Started:	Stopped:	
DROPERIDOL (Interaction)		Reason: Otr spec symp psychopathol nec	
Injection	5.0 Milligram	As necessary Intramuscular	
Batch:	Started:	Stopped:	
Abilify (Interaction)		Reason: Otr spec symp psychopathol nec	
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started: 26/11/2003	Stopped : 05/12/2003	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Levlen, Ferro-Gradmet, Nicabate, Mylanta. Aripiprazole commenced 1 week prior (26/11/03). Multiple drug interactions many have pre this event.cipitated

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rei	port	Detail	ls:

Case Number: 193274 Seq: 1 Gender: F

Reported: 17/12/2003 Weight: 0.00 Hospitalisation: Age: 17

Onset Date: 05/12/2003 **DOB:** 15/01/1986

Outcome: Recovered 05/12/2003 Causality: Causality possible

Reaction Details:

Medicine Details:

LAMICTAL (Interaction)			Reason:		
Tablet	137.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
DIAZEPAM (Interaction)			Reason:	Otr spec symp psychopathol nec	
Tablet	20.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
EPILIM (Interaction)			Reason:		
Tablet	1000.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Additional Information:

Patient was also taking Levlen, Ferro-Gradmet, Nicabate, Mylanta. Aripiprazole commenced 1 week prior (26/11/03). Multiple drug interactions many have pre this event.cipitated

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:				
Case Number: 193937	Seq: 1		Ger	nder: F
Reported: 16/01/200)4		Wei	ight: 0.00
ospitalisation: Admitted	to hospital			Age: 19
Onset Date: 10/12/200)3		I	OOB:
Outcome: Not yet re	covered		Caus	ality: Causality possible
action Details:				
Preferred Term	Severity	Repo	ort Description	Treatment
xtrapyramidal disorder	prolonged	Extrapyramidal of stiffness, tongue hands.	disorder, akathisa, jaw protrusion and stiff	Ceased Abtlify, given benztropine 1mg/day.
fledicine Details:				
Medicine Details: Abilify (Suspected)		Rea	son:	
	Started:	Rea	son: Stopped:	
Abilify (Suspected) Batch:	Started:			
Abilify (Suspected) Batch:	Started: Started:		Stopped:	
Abilify (Suspected) Batch: LARGACTIL (Suspected)			Stopped:	
Abilify (Suspected) Batch: LARGACTIL (Suspected)			Stopped:	
Abilify (Suspected) Batch: LARGACTIL (Suspected)			Stopped:	
Abilify (Suspected) Batch: LARGACTIL (Suspected)			Stopped:	
Abilify (Suspected) Batch: LARGACTIL (Suspected) Batch:	Started:		Stopped:	
Abilify (Suspected) Batch: LARGACTIL (Suspected)	Started:	Rea	Stopped:	Details

Additional Information:

Patient was also taking tegretol and Largactil.

Medical history was significant for pervasive developmental disorder, petit mal epilepsy, and allergy to ethosuxomide and sodium valproate. The patient was undergoing a course of electroconvulsive therapy at the time of this report.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls	:
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Case Number: 193960 Seq: 1 Gender: M

Reported: 19/01/2004 Weight: 0.00 Hospitalisation: Age: 41

Onset Date: 19/12/2003 **DOB**: 05/04/1962

Outcome: Recovered 21/12/2003 Causality: Causality probable

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Ceased Aripiprazole.

Medicine Details:

Aripiprazole (Suspected) Reason: Unspecified psychosis

Tablet 30.0 Milligram Daily Oral

Batch: Started: 15/12/2003 **Stopped:** 19/12/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 1939	966 Seq	: 1			Gender: M
Reported: 19/0	1/2004				Weight: 121.00
Hospitalisation:					Age : 27
Onset Date: 17/1					DOB : 26/09/1976
Outcome: Rec	overed		13/01/2004		Causality: Causality probable
Reaction Details:		1			
Preferred Te		everity		Description	Treatment
Vomiting	to Do	octor	omiting and diarr	hoea.	Ceased Abilify
Diarrhoea	Requ to Do	uired Visit octor			
Medicine Details:			Reaso	n·	
Injection	OATE (Other drug)		Reaso	n:	Intramuscular
Batch:	,	Started:		Stopped	
Abilify (Suspected)		otartea.	Reaso		
Tablet			rtouse		Oral
Batch:	5	Started: 16/12	2/2003	Stonned	: 11/01/2004
I aboratory Inves	tigations:				
		Date Teste	d Result		Details
Laboratory Inves	tigations:	Date Teste	d Result		Details

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 194604 Seq: 1 Gender: F

Reported: 16/02/2004 Weight: 0.00 Hospitalisation: Age: 34

Onset Date: 09/02/2004 **DOB**: 21/08/1969

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Required Visit to Doctor	Dystonic reaction (stiff lower jaw, swollen tongue, difficulty talking, tightness in throat and stiff sore legs on walking).	
Tongue oedema			

Medicine Details:

CITALOPRAM HYDROBROMIDE (O	ther drug)	Reason: Depre	ession	
Tablet	30.0 Milligram	Daily	Oral	
Batch:	Started:	St	opped:	Contin
LORAZEPAM (Suspected)		Reason: Anxie	ty neurosis	
Tablet	Dose Unspec	cified As necessar	y Oral	
Batch:	Started: 31/12/2003	St	opped:	Contin
Abilify (Suspected)		Reason: Schize	ophrenia	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 31/12/2003	St	opped:	Contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has had a similar reaction to Risperidone 2mg/bd.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 195103 Seq: 1 Gender: M

Reported: 04/03/2004 Weight: 89.50 Hospitalisation: Age: 28Y

Onset Date: 15/01/2004 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		tachycardia, CK increased, muscle	Daily monitoring clinically, second - daily FBE/CK/LFT, cessation of medication.
Blood creatine phosphokinase incr Hyperhidrosis Hyperreflexia Mood swings Muscle rigidity Pyrexia Tachycardia			

Medicine Details:

Aripiprazole (Suspected) Reason: Unspecified psychosis

Tablet 45.0 Milligram Daily Oral

Batch: **Started**: 06/01/2004 **Stopped**: 22/01/2004

Laboratory Investigations:

	<u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	Creatine		01/01/2004	61	
	Creatine		22/01/2004	356	
04/03/2004	Creatine		26/01/2004	238	

Additional Information:

Patient also administered: Sodium valproate, Clonazepam.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Deta	ails:							
Case Numbe	er: 196051	Seq:	1				Gende	er: M
Reporte	d : 29/03/200	4					Weigh	t: 0.00
Hospitalisatio	n:						Ag	e: 41
Onset Dat	:e: 01/09/200	3					DO	B : 14/08/1962
Outcom	e: Recovere	d				C	ausalit	y: Causality possible
Reaction De								
Prefe	erred Term	Se	verity	Repo	rt Desc	ription		Treatment
Pyrexia		Cause prolor inpation hospit	nged n	Query neurolept nuscle aches, ri			ats.	Treatment with diazepam, discontinuation of reboxetine and amisulpride and unspecified dose reduction of paroxetine and periciazine.
Agitation		Cause prolor inpatie hospii	nged					
Chills								
Medicine D Abilify (Suspec				Rea	son:			
Batch:		Si	tarted:			Stopped:		
NEULACTIL (S	uspected)			Rea	son:			
Batch:		9	tarted:			Stopped:		
AROPAX (Susp			tarteu.	Rea	son:	Stoppeu.		
7.1.0.7.1.(0.0)	, , ,							
Batch:		Si	tarted: 03/07	7/2003		Stopped:		
EDRONAX (Sus	spected)			Rea	son: D	epression		
Tablet			8.0 M	lilligram	Daily		Oral	
Batch:		S	tarted: 26/08	/2003		Stopped:	22/01/2	004
Laboratory	Invoctinat	ione:						
Date	Type	Range	Date Tested	d Result			De	etails
	,,	-						
Additional Aripiprazole late			symptoms r	ecurred.				

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Reported: 29/03/	-		Jen	der: M
	/2004		Weig	yht: 0.00
Hospitalisation:			Α	. ge: 41
Onset Date: 01/09/	/2003		D	OB : 14/08/1962
Outcome: Recov	/ered		Causa	lity: Causality possible
Reaction Details:				
Preferred Terr	m Severity	Report Des	scription	Treatment
Insomnia Myalgia Neuroleptic malignant s	Caused or prolonged inpatient hospitalisation cyndrome Caused or			
	prolonged inpatient hospitalisation			
Night sweats				
Medicine Details: Abilify (Suspected)		Reason:		
Ability (Suspected)		Neasoll.		
Batch:	Started:		Stopped:	
NEULACTIL (Suspected)		Reason:		
(**************************************				
Batch:	Started:		Stopped:	
AROPAX (Suspected)		Reason:		
Batch:	Started: 03/0	07/2003	Stopped:	
EDRONAX (Suspected)		Reason:	Depression	
	8.0	Milligram Daily	Oral	
Tablet		,		
Tablet Batch:	Started: 26/0	•	Stopped: 22/01.	/2004
	Started: 26/0	•	Stopped: 22/01	/2004

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:					
Case Number: 196051	Seq: 1			Gender:	M
Reported: 29/03/2004				Weight:	
ospitalisation:				_	
•				Age:	
Onset Date: 01/09/2003			_		14/08/1962
Outcome: Recovered			C	ausality:	Causality possible
eaction Details:					
Preferred Term	Severity	Report Desc	ription		Treatment
Гасhycardia	Caused or prolonged inpatient hospitalisation				
Medicine Details: Abilify (Suspected)		Reason:			
Ability (Suspected)		Reason.			
Batch:	Started:		Stopped:		
NEULACTIL (Suspected)		Reason:			
Batch:	Started:		Stopped:		
AROPAX (Suspected)		Reason:			
Batch:	Started: 03/07/2003		Stopped:		
EDRONAX (Suspected)		Reason: D	epression		
Tablet	8.0 Milligram			Oral	
Batch:	Started: 26/08/2003	24,	Stopped:	22/01/2004	1
_aboratory Investigation			Stopped:	22/01/2004	*

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 196398 Seq: 1 Gender: F

Reported: 13/04/2004 Weight: 50.00 Hospitalisation: Age: 15

Onset Date: 24/03/2004 **DOB**: 06/01/1989

Outcome: Recovered 26/03/2004 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Coverity	Hypotensive (66/26).	Aripiprazole withheld then ceased. IV fluids given but was hard to
Drug interaction			re-establish BP.

Medicine Details:

Medicine Details.			
DROPERIDOL (Interaction)		Reason: Otr spec symp psychopathol nec	
Injection	10.0 Milligram	As necessary Intramuscular	
Batch:	Started:	Stopped:	
Abilify (Interaction)		Reason: Anxiety neurosis	
Tablet	15.0 Milligram	Daily Oral	ļ
Batch:	Started: 04/03/2004	Stopped: 24/03/2004	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Buspirone, Lamictal, Centrum and Olanzapine.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	port	Deta	ails:
----	------	------	-------

 Case Number:
 196570
 Seq: 1
 Gender:
 M

 Reported:
 19/04/2004
 Weight:
 70.0

Reported: 19/04/2004 Weight: 70.00 Hospitalisation: Age: 52

Onset Date: 22/03/2004 **DOB**: 02/01/1952

Outcome: Recovered Causality: Causality probable

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	to Doctor	Patient experienced profuse sweating, immediate severe nausea and vomiting with hiccups.	
Hiccups	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

Aripiprazole (Suspected)		Reason:	Schizophrenia	
Tablet	15.0 Milligram	Daily		Oral
Batch:	Started: 22/03/2004		Stopped:	28/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Detail	s:			
ase Number:	196781	Seq: 1	Gend	er: F
Reported:	23/04/2004		Weigh	nt: 0.00
ospitalisation:	Hospitalisation p	orolonged	Ag	je: 56
Onset Date:			DC	B:
	Recovered		Causali	ty: Causality possible
eaction Detai		T	T	
	ed Term	Severity	Report Description	Treatment
Vomiting		Caused or prolonged inpatient hospitalisation	Severe persistent vomiting resolving after 4 days	
ledicine Det Abilify (Suspected			Reason: Schizophrenia	
Tablet	•,	15.0	Milligram Daily Oral	
Batch:		Started:	Stopped:	
	vestigations:		lod L Doubt 2	otoilo.
Laboratory In		nge Date Test	ted Result D	etails

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 197073	Seq: 1		Gender	
Reported: 06/05/2004			Weight	
ospitalisation:				: 44
Onset Date:			DOE	
Outcome: Unknown			Causality	: Causality possible
eaction Details:				
Preferred Term	Severity	Report De		Treatment
leuropathy peripheral	Pe	eripheral neuropathy	/.	
Medicine Details: Abilify (Suspected) Tablet		Reason:	Unspecified schizophren	ia
Batch:	Started:		Stopped:	
_aboratory Investigatio	nne:			
Date Type	Range Date Tested	Result	Det	ails
Additional Information:	:			
port Run: 01/06/2007 01:52PM	Database: pusime02	ADRS0	004	Page 28 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Gender: F Case Number: 197298 Seq: 1 Weight: 0.00 Reported: 12/05/2004

Hospitalisation: Age: 24Y Onset Date: 27/12/2003 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Mania		Mania, agitation, obsessive thoughts, suicidal ideation.	Ceased Abilift
Agitation			
Obsessive thoughts			
Suicidal ideation			

Medicine Details:

Abilify (Suspected) Reason: Tablet 15.0 Milligram Daily Oral Batch: Started: 25/12/2003

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

One month later, the patient committed suicide.

Past medical history bipolar disorder from the age of 16 and two suicide attempts.

Patient was also taking Quetiapine, Luvox, Topiramate.

Followup information: physician did not believe aripiprazole was the cause of the suicide based on the short course of aripiprazole and the discontinuation one month prior to the suicide.

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Report Details:

Case Number: 197651

Reported: 27/05/2004

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Hospitalisation: Admitte	d to hospital	Age : 99u			
Onset Date:		DOB:			
Outcome: Unknow	/n	Сац	Causality: Causality possible		
eaction Details:	T -	T			
Preferred Term	Severity	Report Description	Treatment		
Mania	Caused or prolonged inpatient hospitalisation	Manic episode.			
Drug ineffective	Caused or prolonged inpatient hospitalisation				
Medicine Details: Abilify (Suspected)		Reason: Schizo-affective	tune nevelue		
Tablet			ral		
Batch:	Started:	Stopped:	riai		
Laboratory Investig					
Date Type	Range Date Test	ted Result	Details		
Additional Informati	on:				
eport Run: 01/06/2007 01:52	PM Database: pusime02	ADRS004	Page 30 of 220		



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	ort	Deta	ails:
-----	-----	------	-------

Case Number:197656Seq: 1Gender:FReported:27/05/2004Weight:0.00Hospitalisation:Admitted to hospitalAge: 34Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion botanor			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Hospitalised

Medicine Details:

Abilify (Suspected)		Reason:	Unspecified ps	sychosis
Tablet		Dose Unspecified		Oral
Batch:	Started:	S TERM	Stopped:	01/05/2004

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
	\sim		-	u	

Case Number: 198164 Seq: 1 Gender: M

Reported: 15/06/2004

Hospitalisation:
Onset Date:

Weight: 0.00
Age: 99u
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation		Sedation.	

Medicine Details:

Abilify (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Lithium and Sodium Valproate.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	port	Deta	ails:
----	------	------	-------

Case Number: 198574 Seq: 1 Gender: M

Reported: 28/06/2004 **Weight:** 103.00

Hospitalisation: Age: 23

Onset Date: 01/06/2004 **DOB**: 01/02/1981

Outcome: Recovered 21/06/2004 Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Insomnia		Profound insomnia, nausea and vomiting. Relapse of schizophrenia.	Abilify ceased. Zyprexa restarted.
Schizophrenia	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

Abilify (Suspected)		Reason: Schiz	cophrenia	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 05/04/2004	S	topped: 15/06/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 198644 Seq: 1 Gender: M
Reported: 02/07/2004 Weight: 55.00
Hospitalisation: Age: 28

Onset Date: 15/06/2004 **DOB:** 27/12/1975

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Caction Betails.	cuction betains:						
Preferred Term	Severity	Report Description	Treatment				
Somnolence		Drowsy, dribbling, shuffling, unsteady, pseudoparkinsonism.	Stopped Abilify				
Drooling							
Gait disturbance							
Parkinsonism							

Medicine Details:

Abilify (Suspected)

Tablet

10.0 Milligram

Daily

Oral

Batch:

Started: 07/06/2004

Stopped: 18/06/2004

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Symptoms worse despite reduction of dose.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 198989
 Seq: 1
 Gender:
 F

 Reported:
 16/07/2004
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 99U
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Abilify ceased.

Medicine Details:

Abilify (Suspected)	F	Reason: Unspecif	ied psychosis	
Tablet	15.0 Milligram	1 time	Oral	
Batch:	Started: 29/05/2004	Stop	ped: 29/05/2004	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

It was reported that this was the patient's first episode of psychosis and she had not had any previous antipsychotic treatment. Had total of 3 seizures.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Reported: 20/07/2004	Case Numb	er: 199249	Seq: 1		Gene	der: F		
Onset Date: Outcome: Unknown Causality: Causality postaction Details: Preferred Term Severity Report Description Treatm Convulsion Nocturnal seizures.	Report	ed: 20/07/2004			Weig	jht: 0.00		
Outcome: Unknown raction Details: Preferred Term Severity Report Description Treatment on value of the properties of th	ospitalisati	on:						
Preferred Term Severity Report Description Treatmonvulsion Nocturnal seizures. Preferred Term Severity Report Description Treatmonvulsion								
Preferred Term Severity Report Description Treatmonvulsion Nocturnal seizures. Iedicine Details: Abilify (Suspected) Reason: Oral					Causa	lity: Causality possible		
Onvulsion Nocturnal seizures. Sedicine Details: Abilify (Suspected) Reason: Oral								
Dedicine Details: Abilify (Suspected) Reason: Oral		ferred Term			escription	Treatment		
Abilify (Suspected) Reason: Oral	onvulsion		N	octurnal seizures.				
Abilify (Suspected) Reason: Oral								
				Reason:	Oral			
Daten. Clarica. Clopped. Contin	Ratch	٠٠	Started:	STERM		Contin		
Aboratory Investigations: Date Type Range Date Tested Result Details				Result		Details		
Date 1990 Range Date 165600 Results	Date	Турс	runge Bate restea	resuit	·	Scialio		
	nal	Information:						
Additional Information:	oort Run: 01/0	6/2007 01:52PM	Database: pusime02	ADRS	004	Page 36 of 220		



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 199361
 Seq: 1
 Gender:
 M

 Reported:
 23/07/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 28

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Arrhythmia, dizziness, fatigue and malaise.	
Dizziness			
Fatigue			
Malaise			

Medicine Details:

Abilify (Suspected)		Reason:	Schizophrenia	
Tablet	1.0	Dose Unspecified Daily	Oral	
Batch:	Started:	S TERM	Stopped:	Continuing

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was on four different medications for 'blood pressure/heart'. He has a history of cardiomyopathy which developed in 1999 while being treated with Clozapine.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 199568 Seq: 1 Gender: F

Reported: 02/08/2004 Weight: 70.00 Hospitalisation: Age: 39

Onset Date: 30/06/2004 **DOB**: 02/01/1965

Outcome: Recovered 25/07/2004 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		Restlessness, muscle stiffness and acute euphonia, nausea.	
	Required Visit to Doctor		
Blood creatine phosphokinase incr	Required Visit to Doctor		
	Required Visit to Doctor		
	Required Visit to Doctor		
	Required Visit to Doctor		

Medicine Details:

LOVAN (Other drug)		Reason:	Depression	
Capsule	100.0 Milligram	Daily		
Batch:	Started: L Ti	ERM	Stopped: 19/07/2004	0
STILNOX (Other drug)		Reason:	Specific disorders of sleep	
Tablet	10.0 Milligram	Daily		
Batch:	Started:		Stopped:	0
Abilify (Suspected)		Reason:		
Tablet	10.0 Milligram	Daily		
Batch:	Started: 28/06/2004		Stopped:	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
02/08/2004	Creatine	(N=25-150)	13/07/2004	217	
02/08/2004	Creatine	(N=25-150)	27/07/2004	136	

Additional Information:

Abilifly was reduced from 10mg/daily to 5mg/daily on 08/07/04 - 12/07/04.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 199568 Seq: 1 Gender: F

Reported: 02/08/2004 Weight: 70.00 Hospitalisation: Age: 39

Onset Date: 30/06/2004 **DOB:** 02/01/1965

Outcome: Recovered 25/07/2004 **Causality:** Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Myalgia	Required Visit to Doctor		
	Required Visit to Doctor		

Medicine Details:

LOVAN (Other drug)	ı	Reason: Depression	
Capsule	100.0 Milligram	Daily	
Batch:	Started: L TE	RM Stopped: 19/07/2004	0
STILNOX (Other drug)	1	Reason: Specific disorders of sleep	
Tablet	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	0
Abilify (Suspected)	ı	Reason:	
Tablet	10.0 Milligram	Daily	
Batch:	Started: 28/06/2004	Stopped:	0

Laboratory Investigations:

Additional Information:

Abilifly was reduced from 10mg/daily to 5mg/daily on 08/07/04 - 12/07/04.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number:199795Seq: 1Gender:FReported:09/08/2004Weight:0.00Hospitalisation:Treated in Accident/Emergency DepartmentAge: 34Y

Onset Date: 01/07/2004 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension	Treated in outpatient department only	Dizziness and fainting, syncopal episodes, loss of consciousness with hypertension and bradycardia.	
Bradycardia	Treated in outpatient department only		
Dizziness	Treated in outpatient department only		

Medicine Details:

TEGRETOL (Other drug)	Reason:		
	Dose Ur	nspecified	
Batch:	Started:	Stopped:	
LAMICTAL (Other drug)		Reason:	
	Dose Ur	nspecified	
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
	Dose Ur	nspecified	
Batch:	Started:	Stopped:	
QUILONUM SR (Other drug)		Reason:	
	1.0 Gram		Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
09/08/2004	Other data				Normal QT interval.

Additional Information:

History: Nodular goiter (hypothyrpidism)

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:	Re	po	rt	De	tai	ls:
-----------------	----	----	----	----	-----	-----

 Case Number:
 199795
 Seq: 1
 Gender:
 F

 Reported:
 09/08/2004
 Weight:
 0.00

Hospitalisation: Treated in Accident/Emergency Department
Onset Date: 01/07/2004

Age: 34Y

DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	Treated in outpatient department only	·	

Medicine Details:

Abilify (Suspected) Reason: Unspecifid affective psychosis

Tablet 10.0 Milligram Daily

Batch: Started: 01/07/2004 Stopped: 02/07/2004

Laboratory Investigations:

Additional Information:

History: Nodular goiter (hypothyrpidism)

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 41 of 220



Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Reported: Hospitalisation:	40/00/0004	Seq: 1		Gena	er: F
-	10/08/2004			Weig	ht: 0.00
				Ag	je : 47
Onset Date:	24/06/2004			DO	DB : 18/08/1956
Outcome:	Recovered wi	thout treatment		Causali	ty: Causality possible
Reaction Detail	ils:				
Preferr	ed Term	Severity	Report Descr	ription	Treatment
Convulsion			Patient experienced seizu friend who witnessed seizu episode witnessed by ED 1700-patient became unrincreased tone & stiffness lasted <10 secs(no incontongue biting), felt unwell, lapsed in and out of constitutions.	zure, further RMO at espsonsive, sthroughout, itinence or nauseated,	No treatment.
Malaise					
Nausea					
Somnolence					
Medicine Det Abilify (Suspected Tablet		15.0	Reason: Ur Milligram 1 time	nspecifid affective ps Oral	sychosis
Batch:		Started:	Willingram Tume	Stopped:	0
I aboutom du					
Laboratory Ir			ed Result	Г	etails
Laboratory In		S: Range Date Test	ed Result	E	etails

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 42 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number:200145Seq:1Gender:MReported:19/08/2004Weight:0.00Hospitalisation:Admitted to hospitalAge:19Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Adrenergic syndrome	prolonged innatient	nervousness, insomnia, rapid pulse, dilated pupils, agitation, raised creatine	Observation and investigation in ICU, cessation of antipsychotics and Reboxetine.
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

 Abilify (Interaction)
 Reason:
 Schizophrenia

 15.0 Milligram
 Daily

 Batch:
 Started: 22/07/2004
 Stopped: 05/08/2004
 0

EDRONAX (Interaction)

Reason: Depression

8.0 Milligram Daily

Batch: Started: 14/05/2004 Stopped: 30/07/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
19/08/2004	Creatine				CPK - 800; CPK - 400; 11/08/2004 CPK - 200
19/08/2004	Echocardiogram				Abnormal Echocardiogram which showed reduction in ejection fraction from 76% to 63% with some inferior/septal hypokinesia.

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:		
Case Number: 20014	5 Seq: 1	Gender: M
Reported: 19/08/2	· ·	Weight: 0.00
ospitalisation: Admitt		Age : 19Y
Onset Date:	·	DOB:
Outcome: Recov	ered	Causality: Causality possible
eaction Details:		
Preferred Term	n Severity	Report Description Treatment
Anxiety	Caused or prolonged inpatient hospitalisation	
Blood creatine phosphol	kinase incr Caused or prolonged inpatient hospitalisation	
Drug interaction	Caused or prolonged inpatient hospitalisation	
Medicine Details:		
Abilify (Interaction)		Reason: Schizophrenia
	15.0 Milli	
Batch:	Started: 22/07/2	2004 Stopped : 05/08/2004 0
EDRONAX (Interaction)		Reason: Depression
	8.0 Milli	
Batch:	Started: 14/05/2	2004 Stopped : 30/07/2004
Laboratory Investiç	gations:	

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 44 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:		
Case Number: 200145	Seq: 1	Gender: M
Reported: 19/08/2004	•	Weight: 0.00
. Hospitalisation: Admitted to ho	spital	Age: 19Y
Onset Date:	•	DOB:
Outcome: Recovered		Causality: Causality possible
Reaction Details:		
Preferred Term	Severity	Report Description Treatment
Echocardiogram abnormal	Caused or prolonged inpatient hospitalisation	
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation	
Insomnia	Caused or prolonged inpatient hospitalisation	
Medicine Details:		
Abilify (Interaction)		Reason: Schizophrenia
	15.0 Milligram	
Batch:	Started: 22/07/2004	Stopped : 05/08/2004 0
EDRONAX (Interaction)		Reason: Depression
	8.0 Milligram	
Batch:	Started: 14/05/2004	Stopped : 30/07/2004
Laboratory Investigations	3 :	
Additional Information:		

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:					
Case Number: 200145	Seq: 1		Ge	ender: M	
Reported: 19/08/2004			We	eight: 0.00	
Hospitalisation: Admitted to hos	pital			Age: 19Y	
Onset Date:	•			DOB:	
Outcome: Recovered			Caus	sality: Causality	possible
Reaction Details:				,	•
Preferred Term	Severity	Report Des	scription	Tre	atment
Myalgia	Caused or prolonged inpatient hospitalisation		·		
Mydriasis	Caused or prolonged inpatient hospitalisation				
Nervousness	Caused or prolonged inpatient hospitalisation				
Medicine Details:					
Abilify (Interaction)		Reason:	Schizophrenia		
	15.0 M	lilligram Daily			
Batch:	Started: 22/07	/2004	Stopped: 05/	/08/2004 0	
EDRONAX (Interaction)		Reason:	Depression		
	8.0 M	lilligram Daily			
Batch:	Started: 14/05.	/2004	Stopped: 30/	/07/2004	
Laboratory Investigations	:				
Additional Information:					

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:						
Case Number: 200145 Reported: 19/08/2004 Hospitalisation: Admitted to hos Onset Date: Outcome: Recovered Reaction Details:		Gender: M Weight: 0.00 Age: 19Y DOB: Causality: Causality possible				
Preferred Term	Severity	Report De	scrintion			Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	report De	эсприон			Treatment
Medicine Details:						
Abilify (Interaction)		Reason:	Schizophrenia			
	15.0 Mi					
Batch:	Started: 22/07/		Stopped:	05/08/2004	0	
EDRONAX (Interaction)		Reason:	Depression			
	8.0 Mi					
Batch:	Started: 14/05/	2004	Stopped:	30/07/2004		
Laboratory Investigations:	•					
Additional Information:						

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Report Details:

Hospitalisation:

Onset Date:

Case Number: 200357

Reported: 27/08/2004

Outcome: Unknown

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

DOB:

Weight: 0.00

Age: 99U

Causality: Causality possible

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

eaction D Pr Constipation	eferred Term						
Constipatior	elelleu rellli	Se	everity	Repo	ort Description		Treatment
	n	Patient also experienced constipation over the last few weeks. Patient had tried Zyban last year and felt constipated					
Hallucinatio	n, auditory		P 2 h to r s P	Patient started to ratient also taking wks ago. Exper allucinations 20 or sleep or upon bock on the roof ymptom more "ratient had tried ot notice audito			
Medicine	Details:						
ZYBAN SR (Rea	son:		
Table	et		D	ose Unspecified		Oral	
Bato	ch:	s	tarted:		Stopped:		0
Abilify (Susp	pected)			Rea	son:		
Table	et		D	ose Unspecified		Oral	
Bato	ch:	s	tarted:		Stopped:		0
aborato	ry Investigat	ions:		_			
Laboratoi Date	ry Investigat Type	ions: Range	Date Tested	l Result		Det	ails
Date		Range	Date Tested	Result		Det	ails



Report Details:

Onset Date:

Case Number: 200429

Reported: 30/08/2004 **Hospitalisation:** Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

DOB:

Weight: 0.00

Age: 21

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Outcome: Unknown			Causality:	Causality possible
leaction Details:				
Preferred Term	Severity	Repor	t Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	her to fall.	tension which caused	
Fall	Caused or prolonged inpatient hospitalisation			
Medicine Details: SOLIAN (Suspected)		Reaso	n:	
Batch:	Started:		Stopped:	
Abilify (Suspected)		Reaso	n:	
Tablet	15.0	Milligram [Daily Oral	
Batch:	Started:		Stopped:	0
Laboratory Investigat	ions:			
Date Type	Range Date Test	ed Result	Deta	ils
Additional Informatio	n:			
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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 200465 Seq: 1 Gender: M

Reported: 01/09/2004 Weight: 0.00
Hospitalisation: Age: 99U
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Patient experienced tardive dyskinesia.	Dose reduced to 15mg.

Medicine Details:

Abilify (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced tardive dyskinesia (TD) while taking other atypical antipsychotics. When put on Aripipazole 15mg, the symptoms subsided. When the dose was increased to 20mg, the TD returned. The dose has since been decreased to 15mg.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

- 1		
Case Number: 200639	Seq: 1	Gender: M
Reported: 08/09/2004		Weight: 0.00

Hospitalisation: Age: 72
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Report Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonia, tongue oedema and speech disorder, drooling.	Ceased Abilify.
Drooling			
Speech disorder			
Tongue oedema			

	•	•	ne	 , LU	 Э.

Abilify (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped: 13/04/2004 0	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has now ceased treatment with Aripiprazole and has experienced a possible relapse. Histrory of: diabetes mellitus, myocardial ischaemia, hypertension, smoker, blood cholesterol increased.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

ase Number: 201046	Seq: 1			Gender:	F
Reported: 22/09/2004				Weight:	80.00
spitalisation:				Age:	37
Onset Date: 25/08/2004				DOB:	09/04/1967
Outcome: Not yet recover	red			Causality:	Causality possible
action Details:					
Preferred Term	Severity	Rep	ort Description	on	Treatment
menorrhoea		Ammenonhea (lactation.	2 periods miss	sed) and	
salactorrhoea		iacialion.			
edicine Details:		Re	ason:		
Tablet	15.0	Milligram	Daily	Oral	
Batch:	Started: 18/			pped:	
aboratory Investigations	s:				
	ange Date Test	ed Result		Detai	is
aboratory Investigations Date Type R		ed Result		Detai	ls



Report Details:

Case Number: 201058

Reported: 22/09/2004 **Hospitalisation:** Admitted to hospital

Onset Date: 15/08/2004

Outcome: Recovered

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

DOB:

Age: 20

Causality: Causality possible

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

eaction Detai								
Preferre	ed Term	Se	verity	Repo	rt Description		Treatmen	t
Psychotic disorder		Cause prolon inpatie hospita	ged o	days of ceasing Aripiprazole. She was also mildly depressive with schizoaffective		land	Benzodiazepines as needed and Aripiprazole recommenced in the hospital.	
Depression		Cause prolon inpatie hospita	ged					
Orug withdrawal	syndrome	Cause prolon inpatie hospit	ged					
Medicine Deta	ails:							
Abilify (Suspected)			Reas		_		7
Tablet					O	ral		
Batch:		Sta	arted:		Stopped:			
<u>aboratory In</u>			Date Teste	d Result		Details	`	
Date	Туре	Range	Date Teste	u Result		Details	5	
Additional Inf	ormation	ı:						



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rei	port	Deta	ils:
-----	------	------	------

 Case Number:
 201458
 Seq: 1
 Gender:
 F

 Reported:
 05/10/2004
 Weight:
 75.00

 Hospitalisation:
 Age: 40

Onset Date: 15/09/2004 **DOB**: 31/12/1963

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
		Increased salivation, tetany and hypertonia.	Abilify ceased.
	Required Visit to Doctor		
	Required Visit to Doctor		

Medicine Details:

Lexapro (Other drug)		Reason:		
Tablet	10.0 Millig	ram Daily		Oral
Batch:	Started:	STERM	Stopped:	0
NEXIUM (Other drug)		Reason:		
Tablet	20.0 Millig	ram Daily		Oral
Batch:	Started:	STERM	Stopped:	0
INDERAL (Other drug)		Reason:		
Tablet	80.0 Millig	ram Daily		Oral
Batch:	Started:	L TERM	Stopped:	
Abilify (Suspected)		Reason:		
Tablet	10.0 Millig	ram Daily		Oral
Batch:	Started: 15/08/20	04	Stopped:	01/10/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	ort	Deta	ils:
-----	-----	------	------

Case Number: 201580 Seq: 1 Gender: M

Reported: 08/10/2004 Weight: 75.00 Hospitalisation: Age: 42

Onset Date: 27/09/2004 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction betails.	1	T	T.
Preferred Term	Severity	Report Description	Treatment
Upper respiratory tract infection	Treated in outpatient department only	note described as "upper respiratory tract symptoms" coinciding with prescription of Aripiprazole.	Referred to GP
Drug ineffective	Treated in outpatient department only		

Medicine Details:

Abilify (Suspected)	F	Reason: Unspeci	ified psychosis
Tablet	15.0 Milligram	1 time	Oral
Batch:	Started: 27/09/2004	Stop	oped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number:	004:									
	201751	Sec	j : 1				Gende	er: M		
Reported: 15/10/2004						Weigh	it: 0.00)		
ospitalisation:							_	e : 23Y	,	
Onset Date:						_	DO			
Outcome:		d		26/09/2004	•	C	ausalit	t y: Cau	isality proba	able
eaction Detail		1 0	,							
Preferre	d Term	<u> </u>	Severity	·	ort Descrip				Treatmen	t
Restlessness				Patient develop sit still, and hice	ed restlessn cups.	iess unat	ole to	Ceased	Ability	
Hiccups										
ledicine Deta										
				Re	ason:					
AVANZA (Other dru				Re Milligram						
AVANZA (Other dru Batch:	ng)		30.0 Started:	Milligram	s	Stopped:				
AVANZA (Other dru Batch:	ng)	:	Started:	Milligram Re	sason:	Stopped:				
AVANZA (Other dru Batch: PAXAM (Other drug	ng)		Started: 4.0	Milligram	s ason:					
AVANZA (Other dru Batch: PAXAM (Other drug Batch:	a) 18)		Started:	Milligram Re Dose Unspecified	s ason:	Stopped:				
AVANZA (Other dru Batch: PAXAM (Other drug Batch:	a) 18)		Started: 4.0 Started:	Milligram Re Dose Unspecified	s ason:					
Batch: PAXAM (Other drug Batch: SOLIAN (Other drug	a) 18)		Started: 4.0 Started: 400.0	Milligram Re Dose Unspecified	sason:	Stopped:	20/09/2	004		
Batch: PAXAM (Other drug Batch: SOLIAN (Other drug Batch:	g) g)		Started: 4.0 Started:	Milligram Re Dose Unspecified Re Milligram	sason:		20/09/2	004		
Batch: PAXAM (Other drug Batch: SOLIAN (Other drug	g) g)		Started: 4.0 Started: 400.0 Started:	Milligram Re Dose Unspecified Re Milligram	sason: sason:	Stopped:	20/09/2 Oral	004		
Batch: PAXAM (Other drug Batch: SOLIAN (Other drug Batch: Abilify (Other drug)	g) g)	:	Started: 4.0 Started: 400.0 Started:	Re Dose Unspecified Re Milligram Re Milligram	ason: Sason: Sason:	Stopped:	Oral			
Batch: Batch: Batch: Batch: SOLIAN (Other drug) Batch: Abilify (Other drug) Tablet Batch:	g) g)	.;	Started: 4.0 Started: 400.0 Started:	Re Dose Unspecified Re Milligram Re Milligram	ason: Sason: Sason:	Stopped:	Oral			
Batch: PAXAM (Other drug Batch: SOLIAN (Other drug) Batch: Abilify (Other drug) Tablet Batch:	g) g)	.;	Started: 4.0 Started: 400.0 Started:	Re Dose Unspecified Re Milligram Re Milligram 09/2004	ason: Sason: Sason:	Stopped:	Oral 22/09/2			

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Report Details:

Case Number: 201751

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Reported:	15/10/2004					Weight:	0.00	
ospitalisation:						Age:	23Y	
Onset Date:			DOB:					
Outcome:	Recovered		26/09/2	2004	С	ausality:	Causality proba	able
action Detai	ils:							
ledicine Det Abilify (Other drug				Reason:				
Tablet	3)	10	0 Milligram	Daily		Oral		
Batch:		Started: 2		Dally	Stopped	21/09/2004		
Abilify (Suspected	1)	Starteu. 2	.1/09/2004	Reason:	Stoppeu.	21/09/2004		
Tablet	1)	20	0 Milligram			Oral		
		Started: 2		Daily	Stannadı		0	
Batch:		Started: 2	:3/09/2004		Stoppea:	23/09/2004	0	
aboratory In	voetigatio	one:						
abbratory in	ivesilyalic	JIIS.						
dditional Inf	formation							
aditional III	ormanon.	•						
ort Run: 01/06/200	07 01:52PM	Database: pusime02		ADRS004			Page 57	of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number:202406Seq: 1Gender: MReported:09/11/2004Weight: 105.00Hospitalisation:Admitted to hospitalAge: 29

Onset Date: 06/10/2004 DOB: 21/07/1975

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Details.			1
Preferred Term	Severity	Report Description	Treatment
	prolonged inpatient hospitalisation	syndrome, loss of consciousness,	Treated with Cabergoline. Patient had discontinued all the neuroleptic medications and was taking one of the new anti-parkinsonian drug.
	Caused or prolonged inpatient hospitalisation		
Blood pressure increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details:		
VALIUM (Other drug)		Reason:
Batch:	Started:	Stopped:
Abilify (Suspected)		Reason:
Tablet	45.0 Milligram	Oral
Batch:	Started: 06/10/2004	Stopped: 06/10/2004 0
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 06/09/2004	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
09/11/2004	Creatine		06/10/2004	3770	
09/11/2004	Creatine		07/10/2004	9840	
09/11/2004	Creatine		08/10/2004	8000	
09/11/2004	Creatine		09/10/2004	3160	
09/11/2004	Creatine		14/10/2004	1650	

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg.

He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 202406
 Seq: 1
 Gender:
 M

 Reported:
 09/11/2004
 Weight:
 105.00

Hospitalisation: Admitted to hospital **Age**: 29

Onset Date: 06/10/2004 DOB: 21/07/1975
Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.			
VALIUM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Abilify (Suspected)		Reason:	
Tablet	45.0 Milligram	Oral	
Batch:	Started: 06/10/2004	Stopped: 06/10/2004 0)
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily Oral	
Batch:	Started: 06/09/2004	Stopped:	

Laboratory Investigations:

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg.

He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 202406 Seq: 1 Gender: M

Reported: 09/11/2004 Weight: 105.00

Hospitalisation: Admitted to hospital Age: 29
Onset Date: 06/10/2004 DOB: 21/07/1975

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation		
Loss of consciousness	Caused or prolonged inpatient hospitalisation		
Rebound effect	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)		Reason:		
Batch:	Started:	5	Stopped:	
Abilify (Suspected)		Reason:		
Tablet	45.0 Milligram		Oral	
Batch:	Started: 06/10/2004	5	Stopped: 06/10/2004	0
CLOZARIL (Suspected)		Reason: Uns	pecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral	
Batch:	Started: 06/09/2004	5	Stopped:	

Laboratory Investigations:

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg.

He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 202406 Seq: 1 Gender: M

Reported: 09/11/2004 Weight: 105.00
Hospitalisation: Admitted to hospital Age: 29

Onset Date: 06/10/2004 **DOB**: 21/07/1975

Outcome: Unknown Causality: Causality possible

Reaction Details:

caction betails.								
Preferred Term	Severity	Report Description	Treatment					
Tachycardia	Caused or prolonged inpatient hospitalisation							
Tremor	Caused or prolonged inpatient hospitalisation							

Medicine Details:

VALIUM (Other drug)		Reason:		
Batch:	Started:	Stopp	ped:	
Abilify (Suspected)		Reason:		
Tablet	45.0 Milligram		Oral	
Batch:	Started: 06/10/2004	Stopped: 06/10/2004		0
CLOZARIL (Suspected)		Reason: Unspecifi	ed schizophrenia	
Tablet	200.0 Milligram	Daily	Oral	
Batch:	Started: 06/09/2004	Stop	ped:	

Laboratory Investigations:

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg.

He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report	Details:
--------	----------

Case Number: 202421 Seq: 1 Gender: M
Reported: 09/11/2004 Weight: 68.00
Respitalisation: Hospitalisation prolonged

Hospitalisation: Hospitalisation prolonged **Age**: 68

Onset Date: 27/10/2004 DOB: 10/12/1935
Outcome: Recovered 28/10/2004 Causality: Causality probable

Reaction Details:

<u>reaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	Within 3 hours of first dose presented with dizziness and postural hypotension followed by collapse. Required emergency transfer to general hospital, recoeverd with overnight observation. medication ceased.	Overnight stay in general hospital.
Dizziness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

 Aripiprazole (Suspected)
 Reason:

 10.0 Milligram
 1 time
 Oral

 Batch:
 Started: 27/10/2004
 Stopped: 28/10/2004
 0

Laboratory Investigations:

<u> Luborator</u>	y ilivostiga				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

Case Number: 202421

Reported: 09/11/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 68.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

lospitalisation: Hospitalisation		Age : 68				
Onset Date: 27/10/2004					10/12/1935	
Outcome: Recovered		28/10/2004	C	ausality:	Causality proba	able
eaction Details:						
Preferred Term	Severity	Repor	t Description		Treatmer	ıt
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation					
Medicine Details:						
Aripiprazole (Suspected)		Reaso				
	10.0 M		time	Oral		
Batch:	Started: 27/10	/2004	Stopped:	28/10/2004	0	
Laboratory Investigations	3 :					
Additional Information:						
eport Run: 01/06/2007 01:52PM Da	atabase: pusime02	AD	RS004		Page 63	of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 202498 Seq: 1 Gender: M

Reported: 12/11/2004 Weight: 15.00 Hospitalisation: Admitted to hospital Age: 2

Onset Date: 06/11/2004 DOB: 07/09/2002

Outcome: Recovered 07/11/2004 Causality: Causality possible

Reaction Details:

caction betails.								
Preferred Term	Severity	Report Description	Treatment					
	prolonged inpatient hospitalisation	The child was given an overdose of Aripiprazole 4mg/kg. Only effect was somnolence for 18 hours. Began cardiac monitoring. Child vomited once post charcoal.						

Medicine Details:

Aripiprazole (Suspected) Reason:

Tablet 60.0 Milligram 1 time Oral

Batch: Started: 06/11/2004 **Stopped:** 06/11/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 202697 Seq: 1 Gender: M

Reported: 18/11/2004 Weight: 80.00 Hospitalisation: Age: 25

Onset Date: 15/04/2004 **DOB**: 23/04/1978

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		Patient experienced mild opiate withdrawal symptoms.	Abilify stopped.

Medicine Details:

Abilify (Interaction)		Reason: Unspecified schizophreni	a
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started: 31/03/2004	Stopped: 15/04/200	4
SUBUTEX (Interaction)		Reason:	
Tablet	8.0 Milligram	Daily Oral	
Batch:	Started: 14/01/2004	Stopped:	
ZYPREXA (Other drug)		Reason: Unspecified schizophreni	a
	20.0 Milligram		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	port	Deta	ails:
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Case Number: 202886 Seq: 1 Gender: M

Reported: 19/11/2004 Weight: 94.00 Hospitalisation: Age: 40

Onset Date: 13/11/2004 DOB: 01/02/1964

Outcome: Unknown Causality: Causality possible

Reaction Details:

i <u>toaction Botano.</u>			
Preferred ⁻	Term Severity	Report Description	Treatment
Dyspepsia	Required Vis to Doctor	Patient suffered heartburn, couldn't drink caffeine and had increased shakiness.	
Tremor	Required Vis to Doctor	it	

Medicine Details:

Abilify (Suspected)	F	Reason: Unspecified	d psychosis	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 01/11/2004	Stoppe	d:	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

Case Number: 203073

Reported: 25/11/2004 **Hospitalisation:** Admitted to hospital

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 72.00

Age: 28Y

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Onset Date:		DOB:			
Outcome: Recovered		Causality: Causality possible			
Reaction Details:					
Preferred Term	Severity	Report Description	Treatment		
Blood creatine phosphokinase	e incr Caused or prolonged inpatient hospitalisation	The patient had raised creatine kinase and myositis.			
Myositis	Caused or prolonged inpatient hospitalisation				
Medicine Details: Abilify (Suspected)		Reason:			
Tablet		Oral			
Batch:	Started:	Stopped:	0		
I aboratom / Inventigation					
Laboratory Investigatio	Range Date Test	ed Result Do	etails		
Additional Information:					
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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 203081 Seq: 1 Gender: M

Reported: 25/11/2004 Weight: 0.00 Hospitalisation: Age: 16Y

Onset Date: 29/10/2004 **DOB**:

Outcome: Recovered 03/11/2004 Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Serotonin syndrome: drowsy, tremors, hyperreflexia, increased tone in the limbs, hypertension, increased creatine kinase and bilateral ankle clonus.	Abilify and Fluoxetine were withdrawn.
Blood creatine phosphokinase incr Clonus Hyperreflexia Hypertension Hypertonia			
Somnolence Tremor			

Medicine Details:

FLUOXETINE HYDROCHLORIDE	(Other drug)	Reason:	Anxiety neurosis	
Capsule	30.0 Milligram	Daily	Oral	
Batch:	Started: 17/08/2004		Stopped: 29/10/2004	0
ZYPREXA (Other drug)		Reason:	Otr spec symp psychopathol	nec
	8.0 Milligram	Daily		
Batch:	Started: 10/08/2004		Stopped: 26/10/2004	0
Abilify (Suspected)		Reason:	Otr spec symp psychopathol	nec
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 20/10/2004		Stopped: 29/10/2004	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Adverse reaction occurred not upon initiation of Ability, but when Zyprexa withdrawn. The physician did not consider fluoxetine or olanzapine to be suspect medications. Patient was rechallenged afte eight days with abilify and the same syndrome recurred.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 203122
 Seq: 1
 Gender:
 F

 Reported:
 29/11/2004
 Weight:
 0.00

Hospitalisation: Age: 25

Onset Date: 14/10/2004 **DOB**: 07/05/1979

Outcome: Unknown Causality: Causality possible

Reaction Details:

i todotioni Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Heart disease congenital			Abortion, pregnancy terminated.
Drug exposure during pregnancy Kidney malformation Limb malformation Trisomy 21			

Medicine Details:

OLANZAPINE (Other drug)		Reason:		
Batch:	Started: 01/05/2004		Stopped: 08/07/2004	0
HALOPERIDOL (Other drug)		Reason:		
Batch:	Started: 01/08/2004		Stopped:	0
DICLOXACILLIN SODIUM (Other drug)		Reason:		
Batch:	Started: 10/04/2004		Stopped: 03/06/2004	0
ALPRAZOLAM (Other drug)		Reason:		
Batch:	Started: 01/05/2004		Stopped : 15/05/2004	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
29/11/2004	Other data				At 16 weeks an ultrasound revealed heart (absense of right ventricle) and renal tract abnormalities (left hydronephrosis) and the patient decided to terminate the pregnancy at 19 weeks. This was the patient's second pregancy with no developmental problems with the first child. Amniocentesis revealed no chromosome abnormalities. Follow-up: The foetal heart showed only three chambers with absence of the right ventricle. Only one outflow tract was seen.

Additional Information:

Gravidity 3, parity 1.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	oort	Detai	ls:
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Case Number: 203122 Seq: 1 Gender: F

Reported: 29/11/2004 Weight: 0.00 Hospitalisation: Age: 25

Onset Date: 14/10/2004 **DOB**: 07/05/1979

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.				
Abilify (Suspected)		Reason: L	Inspecified schizophrenia	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 21/06/2004		Stopped: 24/08/2004	0
EFEXOR-XR (Suspected)		Reason:		
Capsule, modified release	75.0 Milligram	Daily	Oral	
Batch:	Started: 07/01/2004		Stopped:	0

Laboratory Investigations:

<u>Laborator</u>	y ilivestigat	110113.			
Date	Туре	Range	Date Tested	Result	Details
					Foetal heart beat was 129 bpm. There was a marked hydronephrosis of the left kidney. Right renal outline was difficult to identify, but the kidney was probably short being at about the fifth percentile measuring 16 mm long. There was a prominant tubular structure in the abdomen which was probably a dilated left ureter. There was absence of the middle phalanx of the little finger of the foetal right hand.

Additional Information:

Gravidity 3, parity 1.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 203204 Seq: 1 Gender: F

Reported: 01/12/2004 Weight: 85.00 Hospitalisation: Age: 38Y

Onset Date: 15/09/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction betails.		T	
Preferred Term	Severity	Report Description	Treatment
Akathisia		Became quite restles which developed into akathisia, pt would wake up each morning feeling nauseous then vomit.	
Restlessness	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

Medicine Details.					
LITHICARB (Other drug)		Reason:			
	500.0	Milligram			
Batch:	Started:		Stopped:		
ZOLOFT (Other drug)		Reason:			
	8.0	Milligram			
Batch:	Started:		Stopped:		
Abilify (Suspected)		Reason:			
Tablet	1.5	Dose Unspecified Daily	•	Oral	
Batch:	Started: 08/	/09/2004	Stopped:	22/09/2004	2 weeks only

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Smoking 20/day; no alcohol and no illicit drugs.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	oort	Detai	ls:
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 Case Number:
 203229
 Seq: 1
 Gender:
 M

 Reported:
 02/12/2004
 Weight:
 0.00

 Hospitalisation:
 Age:
 99U

 Onset Date:
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Vision blurred		Patient developed difficulty focusing and increased, rapid blinking. He also experienced cramping and continuous movement of the tongue. Abilify was ceased.	Abilify dose reduced to 3.5mg/day. Had Botox in his eyelids.
Corneal reflex decreased			
Dyskinesia			
Muscle spasms			

Medicine Details:

Abilify (Suspected)			Reason:		
Tablet	15.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient could no longer work.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rei	port	Detail	ls:

Case Number: 203308 Seq: 1 Gender: F

Reported: 06/12/2004 Weight: 54.00 Hospitalisation: Age: 18Y

Onset Date: 08/10/2004 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Death	Treated in outpatient department only		
Dystonia	Treated in outpatient department only	,	Treated at accident and emergency department with intramuscular cogentin which relieved the adverse reaction

Medicine Details:

Miculcine Details.				
CITALOPRAM HYDROBROMIDE (Other	drug)	Reason:		
Capsule	20.0 Milligram	1 time	Oral	
Batch:	Started: 20/08/2004	Stop	ped:	
Abilify (Suspected)		Reason: Unspeci	fied psychosis	
Capsule	15.0 Milligram	1 time	Oral	
Batch:	Started: 06/10/2004	Stop	ped: 08/10/2004	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 203530 Seq: 1 Gender: F

Reported: 14/12/2004 Weight: 55.00 Hospitalisation: Age: 86

Onset Date: 25/10/2004 DOB: 28/12/1917

Outcome: Recovered 05/11/2004 Causality: Causality probable

Reaction Details:

toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Bradykinesia	Required Visit to Doctor	Patient developed bradykinesia, mild rigidity and mild parkinsonism.	Ceased Aripiprazole.
Muscle rigidity	Required Visit to Doctor		
Parkinsonism	Required Visit to Doctor		

Medicine Details:

THYROXINE SODIUM (Other drug)			Reason:	Myxedema	
Tablet	100.0	Microgram	Daily		Oral
Batch:	Started:	L	TERM	Stopped:	
DIGOXIN (Other drug)			Reason:	Otr&nos disord	of heart rhythm
	62.0	Microgram	Daily		
Batch:	Started:	L	TERM	Stopped:	
OSTELIN 1000 (Other drug)			Reason:	Other diseases	of bone
	1000.0		Daily		
Batch:	Started:	L	TERM	Stopped:	
CALTRATE (Other drug)			Reason:	Other diseases	of bone
Tablet	600.0	Milligram	Daily		Oral
Batch:	Started:	L	TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Reported: 14/12/2004 lospitalisation: Onset Date: 25/10/2004 Outcome: Recovered eaction Details:	05/11/2004		Weight: 55.00 Age: 86 DOB: 28/12/1917 Causality: Causality probable		
edicine Details:					
Aripiprazole (Suspected)	40.0 Millians	Reason: Unspecified			
Tablet Batch:	10.0 Milligram Started: 20/10/2004	Daily	Oral : 25/10/2004		
aboratory Investigations:					
dditional Information:					
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Case Number: 203686

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Reported: 21/12/2004				nt: 0.00
ospitalisation:				je : 99U
Onset Date:			DC	
Outcome: Not yet recove	ered		Causali	ty: Causality probable
action Details:	T -	T		
Preferred Term	Severity	Report Des		Treatment
euroleptic malignant syndrome		Patient experienced ne syndrome which was co serious.	uroleptic malignant onsidered medically	Abilify ceased.
ledicine Details: Abilify (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:		Stopped:	
aboratory Investigation				
Date Type F	Range Date Test	ted Result	D	etails
	1			
Additional Information:				



Case Number: 203689

Reported: 21/12/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Repor Patient experience symptoms.	rt Description ed extrapyramida		Causality possible Treatment
Patient experience symptoms.	rt Description ed extrapyramida		
Patient experience symptoms.	ed extrapyramida		Treatment
Patient experience symptoms.	ed extrapyramida		Treatment
symptoms.			
Reasc	on:		
Reaso	on:		
Reasc	on.		
	Stopped	:	
Reaso	on:		
	Stopped	:	
Reaso	on:		
		Oral	
		:	
		01	
	-		
1/2004	Stopped	:	
ed Result		Details	
	Reas Reas Milligram 1/2004	Stopped Reason: Stopped Reason: Milligram Daily 1/2004 Stopped	Stopped: Reason: Oral Stopped: Reason: Willigram Daily Oral 1/2004 Stopped:



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:					
Case Number: 203689 Reported: 21/12/2004 Hospitalisation: Admitted to hospi Onset Date: Outcome: Recovered Reaction Details:	Seq: 1			Gender: Weight: Age: DOB: Causality:	0.00 99u
Medicine Details:					
HALOPERIDOL (Suspected)	0.0	NACIE	Reason:	Overl	
Batch:	8.0 Started:	Milligram	Daily	Oral Stopped:	
Laboratory Investigations:					
Additional Information:					

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	etai	ls	:
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 Case Number:
 203840
 Seq: 1
 Gender: M

 Reported:
 30/12/2004
 Weight:
 0.00

 Hospitalisation:
 Age: 41

Onset Date: 16/12/2004 **DOB**: 09/12/1963

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Treated in outpatient department only	Extrapyramidal side effects - tremor, increased muscle tone, cogwheel rigidity, abnormal gait, akathisia. Occurred around 16/12/04 after an increase in aripiprazole from 15mg to 30mg on the 4/11/04. NB: Aripiprazole was started on 30/07/04 at 7.5mg daily, later increased to 15mg on the 17/09/04.	Aripiprazole dose reduced to 15mg daily and olanzapine 5-10mg nocte added.
Akathisia	Treated in outpatient department only		

Medicine Details:

Aripiprazole (Suspected)	R	Reason:				
Tablet	30.0 Milligram	Daily	Oral			
Batch:	Started: 30/07/2004	St	topped:			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	oort	Detai	ls:
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 Case Number:
 204007
 Seq: 1
 Gender: M

 Reported:
 07/01/2005
 Weight:
 0.00

Hospitalisation: Age: 25

Onset Date: 20/04/2004 **DOB**: 28/10/1978

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		20/04/04. Afebrile and all other obs stable. CK 16723 and then 17500 on 22/04/04.	impairment, oral fluids encouraged, urine alkalinised

Medicine Details:

QUETIAPINE (Other drug)		Reason:	
Tablet	600.0 Mil	lligram 2 times	Oral
Batch:	Started:		Stopped:
RANITIDINE (Other drug)		Reason:	
Tablet	150.0 Mil	lligram 2 times	Oral
Batch:	Started:		Stopped:
SODIUM VALPROATE (Other drug)		Reason:	
Tablet	1.0 Gra	am 2 times	Oral
Batch:	Started:		Stopped:
Aripiprazole (Suspected)		Reason:	
Tablet	15.0 Mil	lligram Daily	Oral
Batch:	Started: 07/04/2	2004	Stopped: 22/04/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report	t Details:
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Case Number:204033Seq: 1Gender:FReported:10/01/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 63Y

Onset Date: 12/11/2004 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	prolonged	Parkinsonism or Extrapyramidal syndrome.	Aripiprazole ceased.

Medicine Details:

Abilify (Suspected)

Tablet

Batch:

Reason: Unspecified psychosis

Oral

Stopped: 12/11/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Ren	ort	Deta	ils:
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Case Number: 204112 Seq: 1 Gender: M

Reported: 11/01/2005 **Weight:** 90.00

Hospitalisation: Age: 41
Onset Date: 08/12/2004 DOB:

Outcome: Recovered 15/12/2004 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations	to Doctor	The patient had palpitations, was sweaty and confused after being changed from Solian to Abilify, therefore some co-administration and could be a drug-drug interaction.	
Confusional state	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		

Medicine Details:

Medicine Details.						
Abilify (Interaction)	ı	Reason: Unspecified schizophrenia				
Tablet	30.0 Milligram	Daily Oral				
Batch:	Started: 15/11/2004	Stopped: 10/12/2004				
SOLIAN (Interaction)	1	Reason:				
	400.0 Milligram	Daily Oral				
Batch:	Started: 15/06/2004 STE	ERM Stopped:				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 204205 Seq: 1 Gender: F

Reported: 13/01/2005 Weight: 0.00 Hospitalisation: Age: 22

Onset Date: DOB: 16/01/1982

Outcome: Recovered 15/12/2004 Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		The patient experienced severe Parkinsonian with extrapyramidal side effects and akathisia.	Benztropine ceased.
Akathisia			

Medicine Details:

METFORMIN HYDROCHLORIDE (Other	drug)		Reason:	Diabetes melli	tus
Tablet	2.0	Milligram	Daily		Oral
Batch:	Started: 02/	12/2004		Stopped:	
SODIUM VALPROATE (Other drug)			Reason:		
	1.0	Gram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	
Abilify (Suspected)			Reason:	Unspecified ps	sychosis
Tablet	15.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	07/12/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

sality possible Treatment
sality possible
Treatment
Treatment
1

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
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Case Number: 204340 Seq: 1 Gender: M

Reported: 18/01/2005 **Weight**: 110.00

Hospitalisation: Age: 26

Onset Date: 20/09/2004 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder		When aripiprazole commenced on 20-sep-2004, the patient changed from a messy, disorganised man to one attempting to keep cupboards and drawers immaculately clean in both his and other people's houses (compulsive cleaning). The patient's behaviour then changed to excesive walking (resulting in sunburn, constantly blistering feet and dramatic weight loss).	Treated with 5mg Diazepam at night.

Medicine Details:

Abilify (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 20/09/2004 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rei	port	Deta	ils:
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Case Number: 204583 Seq: 1 Gender: M

Reported: 25/01/2005 **Weight:** 100.00

Hospitalisation: Age: 28

Onset Date: 23/12/2004 **DOB**: 04/02/1976

Outcome: Recovered 07/01/2005 Causality: Causality probable

Reaction Details:

<u>leaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Restlessness		The patient experienced increasing restlessness which was 'almost agonising' and caused irritability and insomnia.	Abilify ceased.
Insomnia	Required Visit to Doctor		
Irritability	Required Visit to Doctor		

Medicine Details:

RISPERDAL (Other drug)		Reason:	Unspecified psychosis
	1.0 Milligram	Daily	
Batch:	Started:		Stopped:
Abilify (Suspected)		Reason:	Unspecified psychosis
-	400 1400		

 Tablet
 10.0
 Milligram
 Daily
 Oral

 Batch:
 Started: 20/12/2004
 Stopped: 04/01/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	port	Deta	ails:
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Case Number:204828Seq: 1Gender:FReported:02/02/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 40

Onset Date: 22/11/2004 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Caused or prolonged inpatient hospitalisation	2 weeks ago noticed mouth lop sided, chewing on tongue subconsciously but consciously aware. Right facial drop and blurred vision.	Abilify ceased.
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Facial paresis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason:	Depression	
	60.0 Milligram			
Batch:	Started: 15/12/2002		Stopped:	
EPILIM (Other drug)		Reason:	Unspecified schizophrenia	
	2.0 Gram		Oral	
Batch:	Started: 15/12/2002		Stopped:	
F.G.F. (Other drug)		Reason:		
	1.0 Dose Unsp	pecified Daily		
Batch:	Started:	S TERM	Stopped:	
Abilify (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started:	S TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report I	Detai	ls:
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Case Number:204828Seq: 1Gender:FReported:02/02/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 40

Onset Date: 22/11/2004 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Caused or prolonged inpatient hospitalisation	·	

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason:	Depression	
	60.0 Milligram			
Batch:	Started: 15/12/2002		Stopped:	
EPILIM (Other drug)		Reason:	Unspecified schizophrenia	
	2.0 Gram		Oral	
Batch:	Started: 15/12/2002		Stopped:	
F.G.F. (Other drug)		Reason:		
	1.0 Dose Unsp	pecified Daily		
Batch:	Started:	S TERM	Stopped:	
Abilify (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started:	S TERM	Stopped:	

Laboratory Investigations:

Additional Information:

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 88 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Num Repor						
	rted: 16/02/2005	Seq: 1		ender: U eight: 0.00 Age: 99U		
Onset D	Date:			DOB:		
Outco	ome: Unknown		Caus	sality: Causality possible		
eaction D						
	eferred Term	Severity	Report Description	Treatment		
Convulsion		Со	nvulsion.			
Medicine Abilify (Susp			Reason:			
Bato	ch:	Started:	Stopped:	Stopped:		
Laborato Date	ry Investigations	S: tange Date Tested	Result	Details		

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 89 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 205410
 Seq: 1
 Gender: M

 Reported:
 21/02/2005
 Weight:
 74.00

Hospitalisation: Age: 46

Onset Date: 15/01/2005 **DOB:** 17/07/1958

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypomania	Required Visit to Doctor	The patient developed hypomania. He had racing thoughts, was overactive and unable to sleep.	
Insomnia	Required Visit to Doctor		
Psychomotor hyperactivity	Required Visit to Doctor		
Thinking abnormal	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Other drug)			Reason:	Unspecified sc	hizophrenia	
	15.0	Milligram	Daily			
Batch:	Started: 01	/03/2004		Stopped:		Continuing.
VENLAFAXINE HYDROCHLORIDE (Of	ther drug)		Reason:	Depression		
	300.0	Milligram	Daily			
Batch:	Started:	L	TERM	Stopped:		
ALPRAZOLAM (Other drug)			Reason:	Anxiety neuros	is	
	500.0	Microgram	Daily			
Batch:	Started:	L	TERM	Stopped:		
Aripiprazole (Suspected)			Reason:	Unspecified sc	hizophrenia	
Tablet	15.0	Milligram	Daily		Oral	
Batch:	Started: 05	/10/2004		Stopped:	15/01/2005	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Past history schizophernia, PTSD and depression but never manic.

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 90 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 205444 Seq: 1 Gender: M

Reported: 22/02/2005 **Weight**: 142.00

Hospitalisation: Age: 28
Onset Date: 10/12/2004 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Headache		The patient developed a severe continuous frontal headache soon after commencing Abilify. It resolved only when the drug was ceased.	Abilify ceased.

Medicine Details:

XANAX (Other drug)			Reason:	Anxiety neuros	sis	
	3.0	Milligram	Daily		Oral	
Batch:	Started:		L TERM	Stopped:		Continuing.
ZOLOFT (Other drug)			Reason:	Depression		
	50.0	Milligram	Daily		Oral	
Batch:	Started:		L TERM	Stopped:		
Abilify (Suspected)			Reason:	Unspecified so	chizophrenia	
Tablet	15.0	Milligram	Daily		Oral	
Batch:	Started: 09/	12/2004		Stopped:	25/01/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to Penicillin.

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 91 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:		
Case Number: 205816	Seq: 1	

 Case Number:
 205816
 Seq: 1
 Gender:
 F

 Reported:
 07/03/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 23Y

Onset Date: DOB:

Outcome: Recovered 01/02/2005 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		The patient developed dystonia and increased CK, delirium/psychosis likely due to withdrawal of Aripiprazole in present of Respiridone depot.	Aripiprazole withdrawn. Treated with Anticholinergic, Clonazepam, oral hydration, supportive.
Blood creatine phosphokinase incr Delirium			
Neuroleptic malignant syndrome			
Pyrexia			
Torticollis			

٨	Λ	e	d	i	c	ir	า	e	D	e	ta	il	s	•
	,,	v	ч		•			·	_	v	ш		•	

Aripiprazole (Interaction)

Tablet

Batch:

Started:

Reason:

Unspecified schizophrenia

Oral

Stopped:

Unspecified schizophrenia

Unspecified schizophrenia

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Currently undergoing treatment for psychosis secondary to schizophrenia. Aripiprazole is drug interaction not suspected.

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 92 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 205845 Seq: 1 Gender: M

Reported: 08/03/2005 Weight: 0.00 Hospitalisation: Age: 43

Onset Date: 31/01/2005 **DOB**: 14/04/1961

Outcome: Recovered 24/02/2005 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased			Withdrew Abilify 30mg and Paroxetine. Monitored WBC.
 	Life threatening		

Medicine Details:

Medicine Details.			
Abilify (Suspected)		Reason: Unspecified so	chizophrenia
Tablet	30.0 Milligram	Weekly	Oral
Batch:	Started: 07/09/2004	Stopped:	18/02/2005 0
GenRx Paroxetine (Suspected)		Reason: Depression	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: 07/09/2004	Stopped:	10/02/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
08/03/2005	Neutrophils		31/01/2005	1.7	
08/03/2005	Neutrophils		15/02/2005	1.65	
08/03/2005	Neutrophils		24/02/2005	2.3	
08/03/2005	White blood cells		31/01/2005	3.3	
08/03/2005	White blood cells		15/02/2005	3.5	
08/03/2005	White blood cells		24/02/2005	4.6	

Additional Information:

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 93 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:				
Case Number: 206124	Seq: 1		Gend	er: F
Reported: 17/03/20	005		Weig	ht: 60.00
ospitalisation:			Ą	ge: 47
Onset Date:			DC	DB : 12/05/1957
Outcome: Recover	red	09/03/2005	Causal	ty: Causality possible
eaction Details:	0	T Brand B		Totaloguet
Preferred Term	Severity		escription	Treatment
Agitation		and a marked tremor	ced extreme agitation.	Settled with ceasing Abilify and Benzodiazepam.
Tremor				·
Medicine Details: EPILIM (Other drug)		Reason:		
Tablet	1.0	Gram	Oral	
Batch:	Started:		Stopped:	
Abilify (Suspected)		Reason:	Unspecified psychosis	•
Tablet		Milligram Dail		
Batch:	Started: 01/	/03/2005	Stopped: 07/03/	2005
· · · · · · · · · · · · · · · · · · ·				
Laboratory Investiga	ations: Range Date Tes	sted Result	C	etails

Report Run: 01/06/2007 01:52PM Database: pusime02 ADRS004 Page 94 of 220



Case Number: 206540

Reported: 02/04/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 80.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Onset Date: 28/12 Outcome: Recordance Preferred Ter Paranoia Orug ineffective Medicine Details: SEROQUEL (Other drug) Batch: NEXIUM (Other drug)	vered	A c p w	he patient had the patient had the lifty, which is souple of weeks.	rt Description been taking a batch of ubject to recall, for a She became quite he had previously bee honths.	commenced, then Haldol.
Preferred Ter Paranoia Prug ineffective Medicine Details: SEROQUEL (Other drug) Batch:	1	T A c p w	Repo The patient had the solution of weeks. aranoid when slycell for several managers.	rt Description been taking a batch of ubject to recall, for a She became quite he had previously bee honths.	Treatment Abilify ceased, Risperidone commenced, then Haldol.
Preferred Terestanoia Trug ineffective ECOUPTE (Other drug) Batch:	m S	T A c p w	the patient had the patient had the later which is souple of weeks. aranoid when slyell for several m	been taking a batch of ubject to recall, for a She became quite ne had previously bee nonths.	Abilify ceased, Risperidone commenced, then Haldol.
edicine Details: EROQUEL (Other drug) Batch:	m S	T A c p w	the patient had the patient had the later which is souple of weeks. aranoid when slyell for several m	been taking a batch of ubject to recall, for a She became quite ne had previously bee nonths.	Abilify ceased, Risperidone commenced, then Haldol.
ug ineffective edicine Details: EROQUEL (Other drug) Batch:		A c p w	bilify, which is souple of weeks. aranoid when slyell for several m	ubject to recall, for a She became quite ne had previously bee nonths.	commenced, then Haldol.
edicine Details: SEROQUEL (Other drug) Batch:		Obstacl	Reas	on: Unspecified psych	hosis
EROQUEL (Other drug) Batch:			Reas	on: Unspecified psych	hosis
SEROQUEL (Other drug) Batch:		Otented	Reas	on: Unspecified psych	hosis
Batch:		Otantada	11000	on Chapcamaa paya	
		0441-			
EXIUM (Other drug)		Started:		Stopped:	
			Reas		
Batch: Started:		Started:	Stopped:		
PITOR (Other drug)			Reas	on:	
Batch:		Started:		Stopped:	
oilify (Suspected)			Reas		hosis
Tablet		15.0 M	_	Daily Or	ral
Batch:		Started: 28/09	/2004	Stopped: 16	6/01/2005
boratory Investi	nations:				
Date Type	Range	Date Tested	l Result		Details



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	port	Deta	ails:
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Case Number: 206608 Seq: 1 Gender: F

Reported: 04/04/2005 Weight: 65.00 Hospitalisation: Age: 59

Onset Date: 20/01/2005 **DOB**: 24/12/1945

Outcome: Recovered 24/02/2005 Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Gait disturbance		The patient developed a shuffling, unsteady gait. Very anxious and unwilling to walk unless necessary. Rigidity of the limbs.	Abilify and Lexapro ceased.
Anxiety Muscle rigidity			

Medicine Details:

Micalcinic Details.			
Abilify (Suspected)		Reason: Unspecified s	chizophrenia
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 31/08/2004	Stopped:	27/01/2005
Lexapro (Suspected)		Reason: Depression	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 06/04/2004	Stopped:	27/01/2005

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 206955
 Seq: 1
 Gender:
 F

 Reported:
 13/04/2005
 Weight:
 0.00

Hospitalisation: Age: 51Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Consumer experienced a psychotic high, too heavy menstrual bleeding, and was harrassed by voices while on Aripiprazole therapy. Patient also experienced grogginess, tiredness, stiff muscles (biceps) and shortness of breath which could be a "touch of asthma or long standing sleep apnoea". Patient had a 3mm tumor on the pituitary. In addition, she reported that the prolactin levels were now normal. Patient also experienced nausea at the beginning but rarely at other times, which strongly resembled morning sickness.	

Medicine Details:

Micalcinic Details.			
Abilify (Suspected)		Reason: Unspecified neurosis	
Tablet		Oral	
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient medical history was significant for elevated prolactin level. had heavy periods for many years. Medical condition: Asthma, sleep apnoea syndrome and blood prolactin increased.

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 97 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1	Gende Weight	: 0.00
Seq: 1	Weight	: 0.00
·	_	
	_	
	Age	: 51Y
	DOE	
	Causality	: Causality possible
	·	
Severity	Report Description	Treatment
	Reason: Unspecified neurosis	
	· ·	
Started:		
	Reason:	
500.0 Milligram	n Daily Oral	
Started:	Stopped:	
S :		
	Started: 500.0 Milligram	Reason: Unspecified neurosis Oral Started: Stopped: Reason: Stopped: Started: Stopped: Started: Stopped: Started: Stopped:

Additional Information:

Patient medical history was significant for elevated prolactin level. had heavy periods for many years. Medical condition: Asthma, sleep apnoea syndrome and blood prolactin increased.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details

Case Number: 206963 Seq: 1 Gender: F

Reported: 13/04/2005 Weight: 93.00 Hospitalisation: Age: 28

Onset Date: 20/03/2005 **DOB**: 02/04/1976

Outcome: Recovered 04/04/2005 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea		Severe nausea after starting Abilify.	Needed Maxolon 10mg.

Medicine Details:

AVAPRO (Other drug)		Reason:	
Tablet	500.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
LUVOX (Other drug)		Reason: Unspecified psychosis	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
Abilify (Suspected)		Reason: Prophylaxis	
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started: 20/03/2005	Stopped: 31/03/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 207107 Seq: 1 Gender: F

Reported: 15/04/2005 Weight: 51.00 Hospitalisation: Age: 21

Onset Date: 30/03/2005 **DOB:** 14/04/1983

Outcome: Recovered 31/03/2005 Causality: Causality possible

Reaction Details:

todotion Botanor								
Preferred Term	Severity	Report Description	Treatment					
Restlessness		Patient experienced restless limbs - feeling of 'blood flowing up and down arms' and restless, subjective feelings, drowsiness and akathesia.	Aripiprazole ceased. Treated with Bentropine.					
Akathisia								
Somnolence								

Medicine Details:

Escitalopram (Other drug)		R	leason:	Depression	
Tablet	10.0	Milligram	Daily		Oral
Batch:	Started: 15/	09/2004		Stopped:	03/01/2005
LEVLEN ED (Other drug)		R	leason:	Contraception	
Tablet	1.0	Dose Unspecifie	ed Daily		Oral
Batch:	Started:			Stopped:	
Aripiprazole (Suspected)		R	leason:	Unspecified so	chizophrenia
Tablet	8.0	Milligram	Daily		Oral
Batch:	Started: 22/	03/2005		Stopped:	30/03/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

At times started to use cannabis to control paranoid feelings, but at other times she felt cannabis "made me paranoid".

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls	:
----	----	----	----	-----	----	---

Case Number:207197Seq: 1Gender:FReported:19/04/2005Weight:0.00Hospitalisation:Treated in Accident/Emergency DepartmentAge: 99u

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Nouvelon Botano:							
Preferred Term	Severity	Report Description	Treatment				
Muscle spasms		The patient developed increased muscle spasms and dystonia while on Aripiprazole.					
Dystonia							

Medicine Details:

Abilify (Suspected)		Reason:		
Tablet	15.0 Milligra	n Daily	Oral	
Batch:	Started:	;	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient was also on concomitant treatment with another antipsychotic medication and was known to be susceptible to extrapyramidal symptoms in the past.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 207465
 Seq: 1
 Gender:
 F

 Reported:
 28/04/2005
 Weight:
 0.00

Hospitalisation: Required a visit to the doctor
Onset Date: 01/09/2004

Onset Date: 01/09/2004

Onset Date: 01/09/2004

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Vomiting		insomnia, muscle spasms, vomiting,	Treatment included vitamin B12 injections, vitamin B supplements, magnesium supplements, and acupuncture.
Anxiety			
Coordination abnormal			
Insomnia			
Muscle spasms			
Myoclonus			

Medicine Details:

Abilify (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 01/09/2004 **Stopped:** 01/09/2004 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient also used a hair product (non-shampoo).

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Ren	ort	Deta	ils:
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 Case Number:
 207465
 Seq: 1
 Gender:
 F

 Reported:
 28/04/2005
 Weight:
 0.00

Hospitalisation: Required a visit to the doctor
Onset Date: 01/09/2004
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

١,	caction betails.								
	Preferred Term	Severity	Report Description	Treatment					
	Nausea								
	Weight decreased								

Medicine Details:

Abilify (Suspected)

Tablet

15.0 Milligram

Daily

Oral

Batch:

Started: 01/09/2004

Stopped: 01/09/2004

0

Laboratory Investigations:

Additional Information:

The patient also used a hair product (non-shampoo).

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:					
Case Number: 207470 Reported: 28/04/2 Hospitalisation: Onset Date:	•	Gender: M Weight: 0.00 Age: 99u DOB:			
Outcome: Unknow	vn		lity: Causality possible		
Reaction Details:					
Preferred Term	Severity	Report Description	Treatment		
Paranoia	Caused or prolonged inpatient hospitalisation	Patient experienced high liver function tes abnormal, creatine kinase levels and paranoia while under treatment with Aripiprazole.	st Abilify discontinued. Patient self-medicated with Aripiprazole 30mg and 45mg.		
Medicine Details:					
Abilify (Suspected)		Reason: Unspecified neurosis	;		
Tablet	15.0	Milligram 1 time Oral			
Batch:	Started:	Stopped:	0		
Laboratory Investig					
Laboratory Investig	ations: Range Date Tes	ted Result	Details		

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 104 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:		
Case Number: 207749	Seq: 1	Gender: M
Reported: 12/05/2005		Weight: 0.00

Hospitalisation: Admitted to hospital **Age:** 32

Onset Date: 15/01/2005

Outcome: Unknown

DOB: 11/08/1972

Causality: Causality possible

Reaction Details:

<u>reaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	ability	Aripriprazole initiated 20mg/day on 15/11/2004, increased to 40mg/day (prescribed overdose)	
Cellulitis	prolonged inpatient hospitalisation	The patient developed cellulitis in the legs and suspected neuroleptic malignant syndrome while on Aripiprazole. The cellulitis was severe and there was concern that amputation may be required.	
Blood creatine phosphokinase incr	Incapacity/dis ability		
Drug prescribing error	Incapacity/dis ability		

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason:			
Batch:	Started:		Stopped:		
LUVOX (Suspected)		Reason:			
Batch:	Started: 15/11/2004		Stopped:	17/04/2005	
Abilify (Suspected)		Reason:			
Tablet	Milligram	Daily		Oral	
Batch:	Started: 15/11/2004		Stopped:	17/04/2005	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Neurologist suspected MacArdlesdisease with widespread myoneurosis founf on the biopsy examination

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 207749 Reported: 12/05/2005 Hospitalisation: Admitted to hospi Onset Date: 15/01/2005 Outcome: Unknown Reaction Details:	Seq: 1	Ago DO	er: M t: 0.00 e: 32 B: 11/08/1972 y: Causality possible
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		
Medicine Details:	(Other drug)	Reason:	
	ζ,		
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	

Reason:

Daily

Stopped: 17/04/2005

Stopped:

Oral

17/04/2005

Laboratory Investigations:

Batch:

Tablet

Batch:

Abilify (Suspected)

Additional Information:

Neurologist suspected MacArdlesdisease with widespread myoneurosis founf on the biopsy examination

Started: 15/11/2004

Started: 15/11/2004

Milligram

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 106 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	port	Deta	ails:
----	------	------	-------

 Case Number:
 207751
 Seq: 1
 Gender:
 F

 Reported:
 12/05/2005
 Weight:
 0.00

Hospitalisation:
Onset Date:
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	prolonged	The patient experienced suspected neuroleptic malignant syndrome while on Aripiprazole.	

Medicine Details:

Abilify (Suspected)		Reason:		
Tablet	30.0 Milligram	Daily	Oral	
Batch:	Started:	Stop	ped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Developementaly delayed

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 107 of 220



Hospitalisation:

Case Number: 208131

Reported: 24/05/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Age: 99U

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Onset Date:					DOB	:	
Outcome: Unknown	า				Causality	: Causality possi	ble
Reaction Details:							
Preferred Term	Sev	erity/	Repo	rt Descript	ion	Treatmen	t
Accidental overdose		ove err be ari has ora hov hari	Patient experienced headaches and an overdose due to a possible dispensing error while on aripiprazole, the patient had been experiencing headaches initially with aripiprazole therapy; however, she has has been doing well. Patient prescribed oral aripiprazole 10mg three times a day; however, the doctor thinks the patient may have been receiving a higher dose of aripiprazole, 20 mg three times a day, due to a possible dispensing error.				
Drug dispensing error							
Medicine Details:							
Abilify (Suspected)			Reas	on:			
Tablet		60.0 Milli	igram	Daily	Oral		
Batch:	Sta	erted:		Si	topped:		
	A ione.						
Laboratory Investiga Date Type		Date Tested	Result		Deta	aile	
Date Type	range	Date rested	result		Dett	A113	
Additional Information	on:						
Report Run: 01/06/2007 01:53F	M Database: pus	sime02	Al	DRS004		Page 108	of 220



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 208131	Seq: 1	Gend	der: F
Reported: 24/05/2005		Weig	ht: 0.00
Hospitalisation:			ge : 99U
Onset Date:			OB:
Outcome: Unknown		Causal	ity: Causality possible
Reaction Details:	T a I		
Preferred Term	Severity	Report Description	Treatment
Headache			
Medicine Details:			
Abilify (Suspected)		Reason:	
Tablet	60.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
Laboratory Investigations:			
g			
Additional Information.			
Additional Information:			



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report	Detail	ls:
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Case Number: 208374 Seq: 1 Gender: M
Reported: 01/06/2005 Weight: 90.00

Hospitalisation: Required a visit to the doctor **Age:** 44

Onset Date: 28/02/2005 DOB: 21/10/1960
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

١,	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Erectile dysfunction		Inability to have an erection or maintain an erection.	Withdrawal of Abilify.	

Medicine Details:

Abilify (Suspected) Reason:

Tablet 15.0 Milligram Daily Oral

Batch: **Started**: 24/02/2005 **Stopped**: 29/05/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 110 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 208511 Seq: 1 Gender: M

Reported: 06/06/2005 Weight: 0.00 Hospitalisation: Age: 29

Onset Date: 23/05/2005 **DOB**: 01/09/1975

Outcome: Recovered 02/06/2006 Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psoriasis	prolonged inpatient hospitalisation	Admitted to hospital with exacerbation of psoriasis. Patient started Abilify 15 mg on 09/03/05 and increased dose to 30mg on 08/04/2005. Patient noticed worsening of psoriasis, previously well controlled. Admitted to hospital on 26/05/05 with exacerbation of skin rash, widespread (over entire body) erythema, blistering, painful and itchy, fine and linear excoriations. Also developed neutropenia on admission	Cessation of aripiprazole. Oral flucloxacillin, Dermeze, Elocon, topical dressings

Medicine Details:

Abilify (Suspected)	Re	eason:	
Tablet	15.0 Milligram	1 time	Oral
Batch:	Started: 09/03/2005	Stopped:	26/05/2005

Laboratory Investigations:

<u> </u>	i ji iii tootiga				
Date	Туре	Range	Date Tested	Result	Details
06/06/2005	Haematology				Neutrophil coint dropped to 1.28 (1.8 to 8), WCC 2.6. CRP on admission 70 (2-10) Normalised

Additional Information:

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Case Number: 208511

Reported: 06/06/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

iospitalisation:					Age: 2		
Onset Date: 23/05/2005						1/09/1975	
Outcome: Recovered		02/06/20	06	С	ausality: C	ausality proba	able
eaction Details:							
Preferred Term	Severity	R	eport Desc	ription		Treatmer	t
Blister	Caused or prolonged inpatient hospitalisation						
Erythema	Caused or prolonged inpatient hospitalisation						
Excoriation	Caused or prolonged inpatient hospitalisation						
Madiaina Dataila.							
Medicine Details: Abilify (Suspected)			Reason:				
Tablet	15 O M	/lilligram	1 time		Oral		
Batch:	Started: 09/03		i uiile	04 1-	26/05/2005		
Laboratory Investigations	:						
Additional Information:							
port Run: 01/06/2007 01:53PM Dat	tabase: pusime02		ADRS004			Page 112	of 220



Case Number: 208511

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Reported: 06/06/2005					vveign	t: 0.00	
Hospitalisation:					Age	e: 29	
Onset Date: 23/05/2005					DOI	B : 01/09/1975	
Outcome: Recovered		02/06/200	06	С	ausalit	y: Causality prob	able
Reaction Details:							
Preferred Term	Severity	R	eport Desc	ription		Treatme	nt
Neutropenia	Caused or prolonged inpatient hospitalisation						
Pruritus	Caused or prolonged inpatient hospitalisation						
Medicine Details: Abilify (Suspected)			Reason:				
Tablet	15.0		teason: 1 time		Oral		
Batch:	Started: 09/0	Milligram	i ume	Stopped:		005	
Laboratory Investigations	s:						
Additional Information:							
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Case Number: 208524

Reported: 06/06/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Hospitalisat	tion:					Ag	je: 60Y	
Onset D						DC		
	ome: Unknown					Causali	ty: Causality poss	ible
Reaction D								
	eferred Term		everity		ort Desc	•	Treatmer	nt
Hypertension	on	Incapa ability	r A	Patient was sw Abilify 10 mg tv iigh blood pres leadache.	itched from vice daily ssure of 17	m olanzapine to and developed 70/130 mmHg and		
Headache		Incapa ability	acity/dis					
Medicine MONOPLUS	Details:			Re	ason:			
Bate	ch:	St	tarted:			Stopped:		
Abilify (Susp	pected)			Re	ason:			
Tabl	et		20.0 M	1illigram	Daily	Oral		
Bate	ch:	St	tarted:			Stopped:		
Laborato Date	ry Investigati	ons:	Date Tester	d Result	Ī	D	etails	
	,							
Additiona	al Information	1:						
eport Run: 01/	/06/2007 01:53PM	Database: pu	usime02		ADRS004		Page 114	of 220



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Hospitalisation: Onset Date	: 15/06/200 Admitted	to hospital)5	1			Weig Aç DC	ler: M ht: 0.00 ge: 67 DB: 25/04/1938 ity: Causality possible
Reaction Deta	•	COVERCU				Oddsan	ity: Gausanty possible
	red Term	Se	verity	Reno	rt De	scription	Treatment
Parkinsonism		Cause prolon inpatie	ed or Pa	atient became	akinet sonise isons	ic, psychomotor d, cogwheel rigidity, disease, conciding	Aripiprazole and Carbamazepine ceased.
Cogwheel rigidit	у	Cause prolon inpatie hospit	iged				
Locked-in syndr	ome	Cause prolon inpatie hospit	iged				
Medicine De	tails:						
SODIUM VALPRO		drug)		Reas	son:		
Batch:		St	arted:			Stopped:	
ATORVASTATIN	(Other drug)			Reas	son:	Othr&unspec metabol	ic diseases
Batch:		St	arted:			Stopped:	0
RISPERIDONE (C	ther drug)			Reas	son:	Unspecified psychosis	3
Batch:		St	arted:			Stopped:	0
BENZYDAMINE H	IYDROCHLOF	RIDE (Other drug	J)	Reas	son:		
Batch:		St	arted:			Stopped:	
Laboratory I	nvocticat	ione					
Date	Type	Range	Date Tested	Result			etails
	71	3					
Additional In			sensitive to o	ther antipsych	otics	including Olanzapine	

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

eport Details:		
Case Number: 208709	Seq: 1	Gender: M
Reported: 15/06/2005		Weight: 0.00
ospitalisation: Admitted to	hospital	Age: 67
Onset Date: 24/05/2005		DOB : 25/04/1938
Outcome: Not yet reco	vered	Causality: Causality possib
eaction Details:		
Preferred Term	Severity	Report Description Treatment
sychomotor retardation	Caused or prolonged inpatient hospitalisation	
Iodicino Dotails:		
		Reason:
	Started:	Reason:
F.G.F. (Other drug) Batch:		
F.G.F. (Other drug) Batch:		Stopped:
F.G.F. (Other drug) Batch: METFORMIN HYDROCHLORIDE (Batch:	Other drug)	Stopped: Reason: Diabetes mellitus
F.G.F. (Other drug) Batch: METFORMIN HYDROCHLORIDE (Batch:	Other drug)	Stopped: Reason: Diabetes mellitus Stopped: 0
METFORMIN HYDROCHLORIDE (Batch: CAPTOPRIL (Other drug)	Other drug) Started:	Stopped: Reason: Diabetes mellitus Stopped: 0 Reason: Essential benign hypertension
F.G.F. (Other drug) Batch: METFORMIN HYDROCHLORIDE (Batch: CAPTOPRIL (Other drug) Batch:	Other drug) Started:	Stopped: Reason: Diabetes mellitus Stopped: 0 Reason: Essential benign hypertension Stopped: 0
F.G.F. (Other drug) Batch: METFORMIN HYDROCHLORIDE (Batch: CAPTOPRIL (Other drug) Batch: GLIMEPIRIDE (Other drug)	Other drug) Started: Started:	Stopped: Reason: Diabetes mellitus Stopped: 0 Reason: Essential benign hypertension Stopped: 0 Reason: Diabetes mellitus

Additional Information:

Patient history: Patient has previously been sensitive to other antipsychotics, including Olanzapine.

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Additional Information:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number:	208709	Seq: 1	I			Gender:	M	
Reported:	15/06/2005					Weight:	0.00	
spitalisation:	Admitted to hospi	tal				Age:	67	
Onset Date:	24/05/2005					DOB:	25/04/1938	
Outcome:	Not yet recovered				С	ausality:	Causality pos	sible
action Detail	s:							
lodicino Dota	ile:							
				Reason:	Other coagula	tion defects		
				Reason:	Other coagular	tion defects		
		Star	rted:	Reason:	Other coagular	tion defects	0	
ASPIRIN (Other dru Batch:	g)	Star	rted:	Reason:			0	
ASPIRIN (Other dru Batch:	g)	Star	rted:		Stopped:		0	
ASPIRIN (Other dru Batch: CLONAZEPAM (Oth Batch:	ner drug)		rted: rted:		Stopped:		0	
ASPIRIN (Other dru Batch: CLONAZEPAM (Oth Batch:	ner drug)				Stopped: Otr spec symp	o psychopath	0	
Batch: CLONAZEPAM (Oth Batch: Levodopa-Bensera	ner drug)	Star	rted:	Reason:	Stopped: Otr spec symp Stopped: Paralysis agita	o psychopath	0	
Batch: CLONAZEPAM (Other dru Batch: Levodopa-Bensera Batch:	ner drug) zide (Other drug)	Star		Reason:	Stopped: Otr spec symp Stopped:	o psychopath	0	
Batch: CLONAZEPAM (Other dru Batch: Levodopa-Bensera Batch: LITHIUM CARBONA	ner drug) zide (Other drug)	Star	rted: rted:	Reason:	Stopped: Otr spec symp Stopped: Paralysis agita	o psychopath	0	
CLONAZEPAM (Oth Batch: Levodopa-Bensera	ner drug) zide (Other drug)	Star Star	rted:	Reason:	Stopped: Otr spec symp Stopped: Paralysis agita Stopped:	o psychopath	0 nol nec	

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Patient history: Patient has previously been sensitive to other antipsychotics, including Olanzapine.



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	ort	Detail	ls:
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 Case Number:
 208709
 Seq: 1
 Gender: M

 Reported:
 15/06/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 67
Onset Date: 24/05/2005
DOB: 25/04/1938

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.			
CARBAMAZEPINE (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 23/05/2005	Stopped:	25/05/2005
Aripiprazole (Suspected)		Reason: Unspecified pa	sychosis
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 12/05/2005	Stopped:	26/05/2005

Laboratory Investigations:

Additional Information:

Patient history: Patient has previously been sensitive to other antipsychotics, including Olanzapine.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 208789 Seq: 1 Gender: M

Reported: 20/06/2005 Weight: 0.00 Hospitalisation: Age: 68Y

Onset Date: 24/05/2005 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression	Caused or prolonged inpatient hospitalisation	Four days after the patient's dosage of Aripiprazole was increased to 30mg he was admitted to hospital suffering neuroleptic malignant syndrome secondary to Aripiprazole. He had combative aggressive behaviour, was incoherent, disoriented, hallucinating, had marked rigidity, twitching, tremor, increased blood pressure and fever.	Aripiprazole ceased.
Blood pressure increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GALANTAMINE HYDROBROMIDE (Other	drug)	Reason: Unspecified psychosis
	40.0 Milligram	Oral
Batch:	Started:	Stopped:
Levodopa-Benserazide (Other drug)		Reason: Paralysis agitans
		Oral
Batch:	Started:	Stopped:
TRAMAL SR (Other drug)		Reason: Unspecified schizophrenia
	400.0 Milligram	Oral
Batch:	Started:	Stopped:
Aripiprazole (Suspected)		Reason: Unspecified schizophrenia
Tablet	30.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Dose increased to 30mg 4 days before admission. Levy body dementia.

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 119 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 208789 Seq: 1 Gender: M

Reported: 20/06/2005 Weight: 0.00 Hospitalisation: Age: 68Y

Onset Date: 24/05/2005 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Disorientation	Caused or prolonged inpatient hospitalisation		
Hallucination	Caused or prolonged inpatient hospitalisation		
Incoherent	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GALANTAMINE HYDROBROMIDE (Other drug) Reason: Unspecified psychosis Batch: Started: Stopped: Levodopa-Benserazide (Other drug) Reason: Paralysis agitans Oral Batch: Started: Stopped: Stopped: Unspecified schizophrenia TRAMAL SR (Other drug) Reason: Unspecified schizophrenia Batch: Started: Started: Stopped: Stopped: Stopped: Unspecified schizophrenia Aripiprazole (Suspected) Reason: Unspecified schizophrenia Tablet 30.0 Milligram Daily Oral	Jilic Details.			
Batch: Started: Stopped: Paralysis agitans Oral Batch: Started: Started: Stopped: Oral Batch: Started: Stopped: Stopped: Oral TRAMAL SR (Other drug) Reason: Unspecified schizophrenia Oral Batch: Started: Stopped: Stopped: Oral Aripiprazole (Suspected) Reason: Unspecified schizophrenia Oral Tablet 30.0 Milligram Daily Oral	NTAMINE HYDROBROMIDE (Other dru	g)	Reason:	Unspecified psychosis
Levodopa-Benserazide (Other drug) Reason: Paralysis agitans Oral Batch: Started: Stopped: TRAMAL SR (Other drug) 400.0 Milligram Unspecified schizophrenia Oral Batch: Started: Stopped: Aripiprazole (Suspected) Tablet Reason: Unspecified schizophrenia Unspecified schizophrenia Oral		40.0 Milligram		Oral
Batch: Started: Stopped: TRAMAL SR (Other drug) Reason: Unspecified schizophrenia 400.0 Milligram Oral Batch: Started: Stopped: Aripiprazole (Suspected) Reason: Unspecified schizophrenia Tablet 30.0 Milligram Daily Oral	Batch:	Started:		Stopped:
Batch: Started: Stopped: TRAMAL SR (Other drug) 400.0 Milligram Oral Batch: Started: Stopped: Aripiprazole (Suspected) Tablet 30.0 Milligram Daily Oral	opa-Benserazide (Other drug)		Reason:	Paralysis agitans
TRAMAL SR (Other drug) 400.0 Milligram Oral Batch: Started: Stopped: Aripiprazole (Suspected) Tablet 30.0 Milligram Daily Oral				Oral
Aripiprazole (Suspected) Tablet A00.0 Milligram Au00.0 Milligram Oral Stopped: Reason: Unspecified schizophrenia Daily Oral	Batch:	Started:		Stopped:
Batch: Started: Stopped: Aripiprazole (Suspected) Tablet 30.0 Milligram Daily Stopped: Unspecified schizophrenia Oral	AL SR (Other drug)		Reason:	Unspecified schizophrenia
Aripiprazole (Suspected) Tablet Reason: Unspecified schizophrenia Daily Oral		400.0 Milligram		Oral
Tablet 30.0 Milligram Daily Oral	Batch:	Started:		Stopped:
3,	razole (Suspected)		Reason:	Unspecified schizophrenia
	Tablet	30.0 Milligram	Daily	y Oral
Batch: Started: Stopped:	Batch:	Started:		Stopped:

Laboratory Investigations:

Additional Information:

Dose increased to 30mg 4 days before admission. Levy body dementia.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 208789 Seq: 1 Gender: M

Reported: 20/06/2005 Weight: 0.00 Hospitalisation: Age: 68Y

Onset Date: 24/05/2005 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity	Caused or prolonged inpatient hospitalisation		
Muscle twitching	Caused or prolonged inpatient hospitalisation		
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GALANTAMINE HYDROBROMIDE (Other of	drug)	Reason: Unspecified psychosis
	40.0 Milligram	Oral
Batch:	Started:	Stopped:
Levodopa-Benserazide (Other drug)		Reason: Paralysis agitans
		Oral
Batch:	Started:	Stopped:
TRAMAL SR (Other drug)		Reason: Unspecified schizophrenia
	400.0 Milligram	Oral
Batch:	Started:	Stopped:
Aripiprazole (Suspected)		Reason: Unspecified schizophrenia
Tablet	30.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Dose increased to 30mg 4 days before admission. Levy body dementia.

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 121 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 208789 Seq: 1 Gender: M

Reported: 20/06/2005 Weight: 0.00 Hospitalisation: Age: 68Y

Onset Date: 24/05/2005 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GALANTAMINE HYDROBROMIDE (Other d	lrug)	Reason: Unspecified psychosis
	40.0 Milligram	Oral
Batch:	Started:	Stopped:
Levodopa-Benserazide (Other drug)		Reason: Paralysis agitans
		Oral
Batch:	Started:	Stopped:
TRAMAL SR (Other drug)		Reason: Unspecified schizophrenia
	400.0 Milligram	Oral
Batch:	Started:	Stopped:
Aripiprazole (Suspected)		Reason: Unspecified schizophrenia
Tablet	30.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Dose increased to 30mg 4 days before admission. Levy body dementia.

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Case Number: 209181

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Repor	ted: 28/06/2005	5				,	Weight:	0.00	
Hospitalisati	on:						Age:		
Onset D	ate:						DOB	: 29/05/1970	
Outco	me: Unknown					Ca	ausality	: Causality possi	ble
Reaction D	etails:								
Pre	eferred Term	Se	verity	Repo	ort Desc	ription		Treatmen	t
Liver functio	n test abnormal		fur He live	e patient expendion test whi er ALT was reper enzymes w per limit of no	le receive corted to ere two t	ing Aripipraz be 300. Oth	zole. ier		
Alanine amir	notransferase in	crease							
Madiaina	Dotoilo								
Medicine Abilify (Susp				Rea	son:				
Table			30.0 Mil		Daily		Oral		
Batc		St	arted:	g	,	Stopped:			
Laborator	v Invostigati	ono:							
	y Investigati Type		Date Tested	Result			Deta	nils	
	,,	J							
Date Type Range Date Tested Result Details Additional Information:									
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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	ort D)etai	ls:
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Case Number: 209215 Seq: 1 Gender: F

Reported: 28/06/2005 Weight: 85.00 Hospitalisation: Age: 33

Onset Date: 23/06/2005 **DOB**: 01/02/1972

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash pruritic		red blotchy rash progressively getting	

Medicine Details:

PARNATE (Other drug)	ı	Reason:	
Tablet	90.0 Milligram	2 times Oral	
Batch:	Started: 01/01/2005	Stopped:	0
NEULACTIL (Other drug)	I	Reason:	
Tablet	10.0 Milligram	Daily Oral	
Batch:	Started: 01/01/2005	Stopped:	0
MONOFEME 28 (Other drug)	!	Reason:	
Tablet	1.0	Daily Oral	
Batch:	Started: 01/11/2004	Stopped:	0
SOLIAN (Other drug)		Reason:	
Tablet	1200.0 Milligram	Daily Oral	
Batch:	Started: 01/03/2003	Stopped:	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Case Number: 209215

Reported: 28/06/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 85.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

spitalisation: Onset Date: 23/06/2005 Outcome: Recovered action Details:			c		33 01/02/1972 Causality proba	able
edicine Details: UILONUM SR (Other drug) Tablet Batch: Dillify (Suspected)	1350.0 Milligram Started: 01/01/2005	Reason: Daily Reason:	Stopped:	Oral		
Tablet Batch: 521631 exp.12/2006	7.5 Milligram Started: 20/06/2005	Daily	Stonned:	Oral 25/06/2005	0	
aboratory Investigations:						
dditional Information:						
rt Run : 01/06/2007	se: pusime02	ADRS004			Page 125	of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 209320 Reported: 30/06/20 ospitalisation:	Seq: 1		Gende	.w. E
•	205		Gende	я. г
lospitalisation:	JU5		Weigh	t : 0.00
			Age	e: 49
Onset Date:			DO	B : 25/09/1955
Outcome: Recover	red		Causalit	y: Causality possible
eaction Details:		1		
Preferred Term	Severity	Report Descr	ription	Treatment
Body temperature increas	ed Incapacity/dis ability	Patient experienced persi significant disability/incap of increased body temper and developed headache hot conditions. Symptoms patient ceased working in conditions.	racity symptoms rature, feeling hot while working in s resolved when	
Feeling hot	Incapacity/dis ability			
Headache	Incapacity/dis ability			
Medicine Details: QUETIAPINE (Other drug)		Reason:		
QUETIAPINE (Other drug) Batch:	Started:		Stopped:	
QUETIAPINE (Other drug)	Started:	Reason: Reason:	Stopped:	
QUETIAPINE (Other drug) Batch:	Started: Started:		Stopped:	
QUETIAPINE (Other drug) Batch: NEXIUM (Other drug)		Reason:		nia
QUETIAPINE (Other drug) Batch: NEXIUM (Other drug) Batch:	Started:	Reason:	Stopped:	nia
Batch: NEXIUM (Other drug) Batch: Abilify (Suspected)	Started:	Reason: Ur Milligram Daily	Stopped:	
Batch: NEXIUM (Other drug) Batch: Abilify (Suspected) Tablet	Started: 15.0 Started: 03/	Reason: Reason: Ur Milligram Daily 10/2003	Stopped: Inspecified schizophre Oral Stopped: 05/02/20	

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 209417 Seq: 1 Gender: M

Reported: 04/07/2005 Weight: 0.00 Hospitalisation: Age: 69Y

Onset Date: 25/05/2005 **DOB:**

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	toaction Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Delirium		The patient experienced delirium and fluctuating level of consciousness.	
	Consciousness fluctuating			

Medicine Details:

MOBIC (Other drug)	Re	ason:	
			Oral
Batch:	Started:	Stopped:	
REMINYL (Suspected)	Re	ason:	
	24.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	24/05/2005
MADOPAR (Suspected)	Re	ason:	
	3.0 Dose Unspecified	d Daily	Oral
Batch:	Started:	Stopped:	24/05/2005
Abilify (Suspected)	Re		
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 17/05/2005	Stopped:	24/05/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History of heavy body.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:				
Case Number: 209417 Reported: 04/07/2005 Hospitalisation:	Seq: 1		Gender: Weight: Age:	0.00 69Y
Onset Date: 25/05/2005 Outcome: Recovered			DOB: Causality:	Causality possible
Reaction Details:				
Medicine Details:	545 dl)	Pagani		
TRAMADOL HYDROCHLORIDE (Suspec	400.0 Millig	Reason: ram Daily	Oral	
Batch:	Started:		Stopped: 24/05/2005	5
Laboratory Investigations:				
Additional Information: History of heavy body.				

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 209673	Seq: 1		Gen	ider: F
Reported: 11/07/200				ght: 0.00
ospitalisation: Admitted	to hospital			\ge: 99u
Onset Date:				OOB:
Outcome: Unknown			Causa	ality: Causality possible
action Details:				T
Preferred Term	Severity		ort Description	Treatment
lausea	Caused or prolonged inpatient hospitalisation	vomiting.	nced severe nausea and	
omiting	Caused or prolonged inpatient hospitalisation			
Medicine Details:				
Abilify (Suspected)			ason:	
Tablet Batch:	10.0 Started:	Milligram	1 time Oral Stopped:	
<u>_aboratory Investigat</u>	ions: Range Date Tes	ted Result		Details
,,,,,	- initial and initial			
Additional Informatio	n:			
ort Run: 01/06/2007 01:53PN	Л Database: pusime02		ADRS004	Page 129 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Repor	t D	etai	ls:
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Case Number: 210099 Seq: 1 Gender: F

Reported: 26/07/2005 Weight: 0.00 Hospitalisation: Age: 17

Onset Date: 10/03/2005 **DOB**: 03/11/1987

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	prolonged	Patient experienced severe nausea and vomiting, dizziness, shaking, drowsiness, sensation of difficulty breathing.	Abilify was ceased.
Dizziness	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Other drug)		Reason:		
Batch:	Started: 12/07/2004	Stop	pped:	
Abilify (Suspected)		Reason: Unspeci	fied neurosis	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 10/03/2005	Stop	ped: 10/03/2005	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
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Additional Information:

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Case Number: 210099

Reported: 26/07/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Hospitalisation:					Age: 1		
Onset Date: 10/03/2005						3/11/1987	
Outcome: Recovered				C	ausality: C	ausality prob	able
Reaction Details:							
Preferred Term	Severity		Report De	scription		Treatmer	nt
Somnolence	Caused or prolonged inpatient hospitalisation						
Tremor	Caused or prolonged inpatient hospitalisation						
Vomiting	Caused or prolonged inpatient hospitalisation						
Medicine Details:							
ZYPREXA (Other drug)			Reason:				
ζ, σ,							
Batch:	Started: 12/0	7/2004		Stopped:			
Abilify (Suspected)			Reason:	Unspecified no	eurosis		
Tablet	10.0	Milligram	Daily		Oral		
Batch:	Started: 10/0	3/2005		Stopped:	10/03/2005		
Laboratory Investigation	ns:						
Additional Information:							
eport Run: 01/06/2007 01:53PM [Database: pusime02		ADRS00)4		Page 131	of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:		
Case Number: 210286	Seq: 1	Gender: F
Reported: 01/08/2005		Weight: 63.80

Hospitalisation: Admitted to hospital **Age**: 71

Onset Date: 16/07/2005 DOB: 13/03/1934
Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	prolonged inpatient hospitalisation	The patient's dosage of Abilify was increased from 5mg on 28 June 2005 to 10mg on 6 July 2005 to 15mg on 13 July 2005. She experienced restricted range of motion of neck movements.	Benztropine given.
	Caused or prolonged inpatient hospitalisation		

Medicine Details:	
EPILIM (Other drug)	Reason:

Batch: Started: Stopped:

ACIMAX (Other drug) Reason:

Batch: Started: Stopped:

FOLIC ACID (Other drug) Reason:

Batch: Started: Stopped: FELODUR ER (Other drug) Reason:

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was already in hospital at the time of reactions. Previous history of EPSE with Risperidone and Amisulpride.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

eport Detail	s:				
Case Number:		Seq: 1		Gender:	F
	01/08/2005	•		Weight:	63.80
-	Admitted to hospi	ital		Age:	
Onset Date:				DOB:	13/03/1934
Outcome:	Recovered			Causality:	Causality possible
eaction Detai	ils:				
Medicine Det					
CARTIA (Other dru	ng)		Reason:		
Batch:		Started:		Stopped:	
Abilify (Suspected	i)		Reason:		
Tablet		15.0 Milligram	Daily	Oral	
Batch:		Started: 28/06/2005		Stopped: 13/07/2008	5
_aboratory In	vestigations:				
-	•				
Additional Int	formation:				
Additional Interest	ly in hospital at the ti	ime of reactions. done and Amisulpride.			

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Case Number: 210293

Reported: 01/08/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

IDE (Other drug	Started:	Patient complaining up and hiseling for 2 min courred up to to touple of month	ason: Stoppe	were d on the bur, this he last	Treatment
IDE (Other drug	Started:	Patient complaining up and hiseling for 2 min courred up to to touple of month	ned that his eyes s vision was fixed that his eyes s vision was fixed that he had an he wice a week in the his.	were d on the bur, this he last	
IDE (Other drug	Started:	Patient complaining up and hiseling for 2 min courred up to to touple of month	ned that his eyes s vision was fixed that his eyes s vision was fixed that he had an he wice a week in the his.	d on the bur, this lee last	Treatment
IDE (Other drug	Started:	Patient complaining up and hiseling for 2 min courred up to to touple of month	ned that his eyes s vision was fixed that his eyes s vision was fixed that he had an he wice a week in the his.	d on the bur, this lee last	Treatment
IDE (Other drug	Started:	ioing up and hi eiling for 2 min occurred up to t ouple of month	s vision was fixed nutes to half an ho twice a week in the s. ason: Stoppe	d on the bur, this lee last	
IDE (Other drug	1)		Stoppe	ed:	
IDE (Other drug	1)		Stoppe	ed:	
IDE (Other drug	1)		Stoppe	ed:	
IDE (Other drug	1)	Rea		ed:	
IDE (Other drug	1)	Rea		ed:	
		Rea			
:			ason:		
:			<u> </u>		
	Started:		Stoppe	ea:	
		Rea	ason:		
;	Started:		Stonne	ed:	
		Rea			
	15.0 M	lilligram	Daily	Oral	
;		-	-	ed:	
			33344		
tions:		Ī	1		
Range	Date Tested	d Result		Deta	ails
11		Started:	Rea 15.0 Milligram Started:	Reason: 15.0 Milligram Daily Started: Stoppe	Reason: 15.0 Milligram Daily Oral Started: Stopped:



Case Number: 210552

Reported: 10/08/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 78.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Outcom action De	erred Term	d S Caus prolo inpa	nged			DOB: 07/03/1984 sality: Causality possible Treatment Indwelling catheter insertion.
action De Pref	etails: erred Term	S Caus prolo inpa	sed or Pa onged tient		ort Description	Treatment
Pref	erred Term	Caus prolo inpa	sed or Pa onged tient		•	
		Caus prolo inpa	sed or Pa onged tient		•	
rinary retent	ion	prolo inpa	onged tient	atient develop	ed urinary retention.	Undwalling cathotor incortion
						Abilify was ceased.
edicine D)etails:					
	HYDROCHLORI	DE (Other drug)	Rea	ason:	
Batch		;	Started:		Stopped:	
ROZAC (Othe	er drug)			Rea	ason:	
Batch	:	;	Started:		Stopped:	
ARIET (Other				Rea	ason:	
Batch		;	Started:		Stopped:	
ALIUM (Other	r drug)			Rea	ason:	
Batch			Started:		Stopped:	
Daton	•	•	Jiai leu.		оторреи.	
	<u>Investigat</u>		T	T		
Date	Туре	Range	Date Tested	Result		Details



Case Number: 210552

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

ospitalisation: Onset Date:				0		20 07/03/1984	:hla
eaction Detai	Recovered Is:			C	ausanty:	Causality poss	ibie
Medicine Deta	aile						
DILOSYN (Suspect			Reason:				
Tablet					Oral		
Batch:		Started:		Stopped:			
Abilify (Suspected)		Reason:				
Tablet		10.0 Milligram	Daily		Oral		
Batch:		Started: 10/12/2004		Stopped:	09/01/2005	i	
Laboratory In	vestigations:						
Additional Inf	ormation:						
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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Repo	ort D	etai	ls:
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Case Number:210553Seq: 1Gender:MReported:10/08/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 48

Onset Date: 08/07/2004 **DOB**: 16/08/1955

Outcome: Recovered Causality: Causality possible

Reaction Details:

reaction betails.	1		
Preferred Term	Severity	Report Description	Treatment
Dysuria	Caused or prolonged inpatient hospitalisation	Patient developed difficulty in passing urine.	Abilify was ceased.
Urinary retention	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.			
CLOZAPINE (Suspected)		Reason: Unspecified p	sychosis
Tablet			Oral
Batch:	Started: 03/06/2004	Stopped:	26/07/2004
Abilify (Suspected)		Reason:	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 03/06/2004	Stopped:	26/07/2004

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
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Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

R	Δ	n	^	rt	n	et	ai	le	•
\mathbf{r}	ㄷ	u	u	IL	ப	EL	aı	13	-

 Case Number:
 210555
 Seq: 1
 Gender: M

 Reported:
 10/08/2005
 Weight: 90.00

Hospitalisation: Age: 23

Onset Date: 01/07/2005 **DOB**: 19/01/1982

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction betails.				
Preferred Term	Severity	Report Description	Treatment	
Oculogyration		receiving Abilify. "upward rolling	Reduce dose of Abilify to 20mg. Benztropine 1-2mg as needed.	

Medicine Details:

Medicine Details.			
CITALOPRAM HYDROBROMIDE	(Other drug)	Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
Abilify (Suspected)		Reason: Unspecified schizophrer	nia
Tablet	30.0 Milligram	Daily Oral	
Batch:	Started: 08/04/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report	Detail	ls:
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Case Number:210565Seq: 1Gender:FReported:10/08/2005Weight:0.00Hospitalisation:Required a visit to the doctorAge: 57

Onset Date: 20/07/2005 **DOB**: 14/08/1947

Outcome: Recovered 27/07/2005 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rhinorrhoea		Patient developed runny nose, blurred vision, agitated, fear, lightheaded, sleep disturbance, mental confusion, skin rash.	Beconase and Hydrocortisone cream.
Agitation Confusional state			
Dizziness Fear			
Rash			
Sleep disorder			
Vision blurred			

Medicine Details:

SOLIAN (Other drug)		Rea	ason:	Unspecified schizophrenia
	400.0 Mil	ligram		

Batch: Started: 01/05/2005 **Stopped:** 29/06/2005

ZYPREXA (Other drug) Reason: Unspecified schizophrenia

5.0 Milligram

Batch: Started: Stopped: 29/06/2005

Abilify (Suspected) Reason:

Tablet 20.0 Milligram Daily Oral

Batch: Started: 13/07/2005 **Stopped:** 26/07/2005

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report	Details:
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Case Number: 211002 Seq: 1 Gender: F

Reported: 22/08/2005 Weight: 65.00 Hospitalisation: Age: 54

Onset Date: 15/01/2005 **DOB**: 19/04/1950

Outcome: Recovered 15/07/2005 Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis	Caused or prolonged inpatient hospitalisation	receiving Aripiprazole 60mg daily.	Aripiprazole ceased, started on Quetiapine.
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Overdose	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZEPAM (Other drug)		Reason: Speci	fic disorders of sleep		
	10.0 Milligram				
Batch:	Started: 01/01/2000	St	topped:		
ZOLOFT (Other drug)		Reason:			
Tablet	150.0 Milligram		Oral		
Batch:	Started: 01/01/2000	St	opped:		
Abilify (Suspected)		Reason:			
Tablet	60.0 Milligram	Daily	Oral		
Batch:	Started: 15/10/2004	St	topped:	0	

Laboratory Investigations:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rei	port	Detail	ls:

Case Number: 211002 Seq: 1 Gender: F

Reported: 22/08/2005 Weight: 65.00 Hospitalisation: Age: 54

Onset Date: 15/01/2005 **DOB**: 19/04/1950

Outcome: Recovered 15/07/2005 Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.				
TEMAZEPAM (Other drug)		Reason:	Specific disorders of sle	ер
	10.0 Milligram			
Batch:	Started: 01/01/2000		Stopped:	
ZOLOFT (Other drug)		Reason:		
Tablet	150.0 Milligram		Oral	
Batch:	Started: 01/01/2000		Stopped:	
Abilify (Suspected)		Reason:		
Tablet	60.0 Milligram	Daily	Oral	
Batch:	Started: 15/10/2004		Stopped:	0

Laboratory Investigations:

Additional Information:

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Case Number: 211097

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

spitalisation: Onset Date: 08/08/2009			Reported: 25/08/2005 Weight: 0.00							
Oneot Dato: 08/08/2008			=	ge : 46						
Oliset Date. 00/00/200.	5			OB : 27/02/1959						
Outcome: Unknown			Causal	ity: Causality possible						
action Details:										
Preferred Term	Severity	Rep	ort Description	Treatment						
achycardia		elevated creatin	nced tachycardia 90-110, ine kinase reported as neuroleptic malignant	Clopine withheld.						
Blood creatine phosphokina	se incr									
leuroleptic malignant syndr										
Pyrexia										
ledicine Details:										
LORAZEPAM (Other drug)			ison:							
Tablet		Milligram	Oral							
Batch:	Started:		Stopped:	0						
CLONAZEPAM (Other drug)		Rea	ison:							
Batch:	Started:		Stopped:							
PARACETAMOL (Other drug)			ason:							
Tablet		Gram	Oral							
Batch:	Started:	Per	Stopped:							
OLANZADINE (Commented)		Milligram	i son: Oral							
OLANZAPINE (Suspected)	20.0		Orai							
Tablet		Willingram	Stannadi	0						
Tablet Batch:	Started:		Stopped:	0						
Tablet	Started:			0 Details						

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number:	211097 25/08/2005	Seq: 1				Gender: Weight:	
Hospitalisation:	23/06/2003					Age:	
Onset Date:	08/08/2005						27/02/1959
Outcome:					С		Causality possible
Reaction Detai							, p
Medicine Deta	ails:						
Aripiprazole (Susp	ected)			Reason:			
Tablet			Milligram			Oral	
Batch:		Started:			Stopped:		0
QUETIAPINE (Susp	pected)			Reason:			
Batch:		Started:			Stopped:		
CLOPINE (Suspect	ted)	Starteu.		Reason:	Stoppeu.		
Tablet	,,	125.0	Milligram	Daily		Oral	
Batch:		Started: 26		·	Stopped:	09/08/2005	5
Laboratory In	vestigations:						
Laboratory III	vestigations.						
Additional Inf	ormation:						
Additional Inf	ormation:						
Additional Inf	ormation:						
Additional Inf	ormation:						
Additional Inf	ormation:						

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
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Case Number:211537Seq: 1Gender:FReported:09/09/2005Weight:0.00Hospitalisation:Required a visit to the doctorAge: 43

Onset Date: 22/08/2005 **DOB**: 13/11/1961

Outcome: Recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hallucination		Patient experienced hallucinations, disorientation, dizziness, faecal incontinence, urinary incontinence, upset stomach, palpitations.	Reduced Abilify to 30mg daily from 50mg.
Overdose		Prescribed dose above recommended	
Disorientation			
Dizziness			
Faecal incontinence			
Palpitations			
Stomach discomfort			
Urinary incontinence			

Medicine Details:

Abilify (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started: 20/08/2005		Stopped: 01/09/2005	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
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Additional Information:

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Case Number: 211932

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Reported: 23/09/2005	-		Weight: 0.00		
ospitalisation:			Age : 99u		
Onset Date:		DOB:			
Outcome: Recovered		(Causality: Causality possible		
action Details:		T			
Preferred Term	Severity	Report Description	Treatment		
euroleptic malignant syndron	ne	The patient developed neuroleptic malignant syndrome while undergo therapy with Aripiprazole and Cloza	Clozapine ceased. ing apine.		
ledicine Details: Abilify (Suspected)		Reason:			
Tablet			Oral		
Batch:	Started:	Stopped:			
CLOZAPINE (Suspected)		Reason:			
Tablet			Oral		
Batch:	Started:	Stopped			
aboratory Investigation	ns: Range Date Test	ed Result	Details		
dditional Information:					



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 212252 Seq: 1 Gender: M

Reported: 05/10/2005 Weight: 80.00 Hospitalisation: Age: 36Y

Onset Date: 23/09/2005 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Patient experienced severe dystonic reaction when Aripiprazole therapy changed from 10mg to 15mg daily.	
Therapy regimen changed			

Medicine Details:

LORAZEPAM (Other drug)		Reason: Otr spec syr	np psychopathol ne	C
Tablet	6.0 Milligram Oral			
Batch:	Started: 19/09/2005	Stopped	l:	
MIDAZOLAM (Other drug)		Reason:		
Injection	10.0 Milligram		Intramuscular	
Batch:	Started: 23/09/2005	Stopped	l:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspecified	psychosis	
(•		
Injection	150.0 Milligram	1 time	Intramuscular	
, ,	150.0 Milligram Started: 23/09/2005	1 time Stopped		
Injection	ŭ		l:	
Injection Batch:	ŭ	Stopped	l:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous dystonic reaction to Haloperidol.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 212584
 Seq: 1
 Gender:
 M

 Reported:
 14/10/2005
 Weight:
 0.00

Hospitalisation:Admitted to hospitalAge: 29Onset Date:06/09/2005DOB: 22/07/1976

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	prolonged inpatient hospitalisation	10mg with addition of Aripiprazole 10mg.	Withdrawal of all antipsychotics, supportive measures monitioring.

Medicine Details:

Micalcinic Details.				
ZYPREXA (Suspected)		Reason:	Paranoid type schizophrenia	
	10.0 Milligram	Daily		
Batch:	Started: 15/07/2003		Stopped : 15/09/2005	0
Abilify (Suspected)		Reason:	Paranoid type schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 15/08/2005		Stopped: 15/09/2005	0

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:								
Case Number: 212584 Seq: 1 Reported: 14/10/2005 Hospitalisation: Admitted to hospital Onset Date: 06/09/2005 Outcome: Recovered			Gender: M Weight: 0.00 Age: 29 DOB: 22/07/1976 Causality: Causality possible				e	
Reaction Details: Preferred Term	Severity		Report De	scription			Treatment	
Blood creatine phosphokinase incr	1		Troport Be	осприот			Tredutient	
Cognitive disorder	Caused or prolonged inpatient hospitalisation							
Muscle twitching	Caused or prolonged inpatient hospitalisation							
Medicine Details:								
ZYPREXA (Suspected)			Reason:	Paranoid type	schizophr	enia		
Batch:	10.0 N Started: 15/07	Milligram 7/2003	Daily	Stopped:	15/09/20	05 0		
Abilify (Suspected)			Reason:	Paranoid type	schizophr	enia		
Tablet	10.0 M	Milligram	Daily		Oral			
Batch:	Started: 15/08	8/2005		Stopped:	15/09/20	05 0		
Laboratory Investigations:								
Additional Information:								

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report	t Detail	s:
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Case Number:212584Seq: 1Gender:MReported:14/10/2005Weight:0.00Hospitalisation:Admitted to hospitalAge: 29

Onset Date: 06/09/2005 **DOB:** 22/07/1976

Outcome: Recovered Causality: Causality possible

Reaction Details:

touotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Medicine Details.				
ZYPREXA (Suspected)		Reason:	Paranoid type schizophrenia	1
	10.0 Milligram	Daily		
Batch:	Started: 15/07/2003		Stopped: 15/09/2005	0
Abilify (Suspected)		Reason:	Paranoid type schizophrenia	l
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 15/08/2005		Stopped: 15/09/2005	0

Laboratory Investigations:

Additional Information:

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 149 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 213135 Seq: 1 Gender: F

Reported: 07/11/2005 Weight: 39.00 Hospitalisation: Age: 34

Onset Date: 04/09/2005 DOB: 16/03/1971

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicilon Details.			
Preferred Term	Severity	Report Description	Treatment
Joint stiffness	Caused or prolonged inpatient hospitalisation	Patient experienced stiff jaw and numb tongue. Previous similar reaction with Risperidone.	Given Benztropine 1mg oral.
Hypoaesthesia oral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: Started: 14/08/2005 S TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous similar reaction with Risperidone.

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Case Number: 213363

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Reported: 14/11/2005			Weigh	t: 0.00		
espitalisation:			_	e: 99u		
Onset Date:		DOB:				
Outcome: Unknown			Causalit	y: Causality possible		
action Details:	0.5. "	D: (5	- winding T	Tourism		
Preferred Term	Severity	Report Des	•	Treatment		
portion spontaneous		The patient became pre Aripiprazole and had a	egnant while taking miscarriage.			
ledicine Details: Abilify (Suspected)		Reason:				
Tablet			Oral			
Batch:	Started:		Stopped:			
RISPERIDONE (Suspected)		Reason:				
Batch:	Started:		Stopped:			
.aboratory Investigatio	P INS: Range Date Tes	sted Result	De	rtails		
Additional Information:						
port Run: 01/06/2007 01:53PM	Database: pusime02	ADRS004	4	Page 151 of 220		



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 213368 Seq: 1 Gender: F

Reported: 14/11/2005 Weight: 0.00 Hospitalisation: Age: 37

Onset Date: 15/10/2005 **DOB**: 05/07/1968

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	The patient was hypotensive, pale, cold and sweaty, complaining of diarrhoea and with low Oxygen levels two weeks after commencing Clozaril. She also had mild renal failure secondary to dehydration.	
Dehydration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

modicino Dotano.					
EPILIM (Other drug)		Reason:			
Batch:	Started:		Stopped:		
AVAPRO (Other drug)		Reason:			
Batch:	Started:		Stopped:		
CLOZARIL (Suspected)		Reason:			
Tablet	250.0 Milligram	Daily		Oral	
Batch:	Started: 10/10/2005		Stopped:	24/10/2005	0
Abilify (Suspected)		Reason:			
Tablet	45.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
14/11/2005	Creatine				360
14/11/2005	Troponin		24/10/2005	0.12	
14/11/2005	White blood cells		24/10/2005	16	pre treatment 13.4

Additional Information:

PMHx, Hypertension, Diabetes Mellitus, Increased cholesterol

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

	Case Number: 213368 Seq: 1			Gender: F		
Reported: 14/11/2005	Weight: 0.00					
ospitalisation:		Age: 37				
Onset Date: 15/10/2005			_	: 05/07/1968		
Outcome: Recovered			Causality:	Causality possible		
eaction Details:						
Preferred Term	Severity	Report Description	on	Treatment		
Diarrhoea	Caused or prolonged inpatient hospitalisation					
Orug ineffective	Caused or prolonged inpatient hospitalisation					
Hyperhidrosis	Caused or prolonged inpatient hospitalisation					
Medicine Details:	prolonged inpatient	Reason				
	prolonged inpatient	Reason:				
Medicine Details:	prolonged inpatient		opped:			
Medicine Details: EPILIM (Other drug)	prolonged inpatient hospitalisation		ppped:			
Medicine Details: EPILIM (Other drug) Batch: AVAPRO (Other drug)	prolonged inpatient hospitalisation Started:	Sto Reason:				
Medicine Details: EPILIM (Other drug) Batch: AVAPRO (Other drug) Batch:	prolonged inpatient hospitalisation	Sto Reason: Sto	opped:			
Medicine Details: EPILIM (Other drug) Batch: AVAPRO (Other drug) Batch: CLOZARIL (Suspected)	prolonged inpatient hospitalisation Started:	Sto Reason: Sto Reason:	pped:			
Medicine Details: EPILIM (Other drug) Batch: AVAPRO (Other drug) Batch: CLOZARIL (Suspected) Tablet	prolonged inpatient hospitalisation Started: Started: 250.0 Milligran	Reason: Sto Reason: Daily	opped: Oral	5 0		
Medicine Details: EPILIM (Other drug) Batch: AVAPRO (Other drug) Batch: CLOZARIL (Suspected) Tablet Batch:	prolonged inpatient hospitalisation Started:	Sto Reason: Sto Reason: Daily Sto	pped:	5 0		
Medicine Details: EPILIM (Other drug) Batch: AVAPRO (Other drug) Batch: CLOZARIL (Suspected) Tablet	prolonged inpatient hospitalisation Started: Started: 250.0 Milligran	Reason: Sto Reason: Daily Sto Reason:	opped: Oral	5 0		

Additional Information:

PMHx, Hypertension, Diabetes Mellitus, Increased cholesterol

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 213368 Reported: 14/11/2005 Hospitalisation: Onset Date: 15/10/2005 Outcome: Recovered	i	Weig Ag D0	ler: F ht: 0.00 ge: 37 DB: 05/07/1968 ity: Causality possible
Reaction Details:	T 2 T		
Preferred Term	Severity	Report Description	Treatment
Nasopharyngitis	Caused or prolonged inpatient hospitalisation		
Oxygen saturation decreased	d Caused or prolonged inpatient hospitalisation		
Pallor	Caused or prolonged inpatient hospitalisation		
Medicine Details:			
EPILIM (Other drug)		Reason:	

Batch: Started: Stopped: AVAPRO (Other drug) Reason: Batch: Started: Stopped: CLOZARIL (Suspected) Reason: Tablet 250.0 Milligram Daily Oral Batch: Started: 10/10/2005 Stopped: 24/10/2005 0 Abilify (Suspected) Reason: Tablet 45.0 Milligram Daily Oral Batch: Started: Stopped:

Laboratory Investigations:

Additional Information:

PMHx, Hypertension, Diabetes Mellitus, Increased cholesterol

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	ort D)etai	ls:
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Case Number:213447Seq:1Gender:FReported:15/11/2005Weight:0.00Hospitalisation:Admitted to hospitalAge:20

Onset Date: DOB: 19/09/1985

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	prolonged inpatient		Humalog IV Infusion due to actrapid ADR, Aripiprazole ceased.
Diabetic ketoacidosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LISINOPRIL (Other drug)		Reason: Dia	abetes mellitus	
	10.0 Milligram			
Batch:	Started:		Stopped:	
INSULIN ASPART (Other drug)		Reason: Dia	abetes mellitus	
Injection	3.0 Millilitre		Subcutaneous	
Batch:	Started:		Stopped:	
INSULIN GLARGINE (Other drug)		Reason: Dia	abetes mellitus	
Injection	10.0 Millilitre	Daily	Subcutaneous	
Batch:	Started:		Stopped:	0
Aripiprazole (Suspected)		Reason:		
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 25/10/2005		Stopped: 01/11/2005	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 213524
 Seq: 1
 Gender:
 F

 Reported:
 17/11/2005
 Weight:
 0.00

 Hospitalisation:
 Age: 43

Onset Date: 02/04/2005 **DOB**: 23/08/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

iteaction Details.			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Neuroleptic Malignant Syndrome. She had increased temperatures, increased	Withheld neuroleptics initially, monitored temperature, BP, pulse, QID. Olanzapine restarted on 7/4/05.
Blood creatine phosphokinase incr			
Hallucination, auditory			
Leukocytosis			
Pyrexia			
Suicidal ideation			

Medicine Details:

Modifile Botalie			
Aripiprazole (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started: 17/03/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
17/11/2005	ALT = SGPT		02/04/2005	61	
17/11/2005	ALT = SGPT		04/04/2005	51	
17/11/2005	ALT = SGPT		11/04/2005	62	
17/11/2005	AST = SGOT		02/04/2005	36	
17/11/2005	AST = SGOT		04/04/2005	37	
17/11/2005	Creatinine		02/04/2005	0.11	
17/11/2005	Creatinine		11/04/2005	0.09	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 213524 Seq: 1 Gender: F

Reported: 17/11/2005 Weight: 0.00 Hospitalisation: Age: 43

Onset Date: 02/04/2005 **DOB**: 23/08/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

MEGICINE DELANS.			
Aripiprazole (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily Oral	
Batch:	Started: 17/03/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		02/04/2005	158	
17/11/2005	GGT = SGGT =		04/04/2005	125	
17/11/2005	GGT = SGGT =		11/04/2005	109	
	Neutrophils		02/04/2005	5.8	
17/11/2005	Neutrophils		11/04/2005	3.7	
17/11/2005	Neutrophils		04/04/2005	4.4	
17/11/2005	Potassium		02/04/2005	4.1	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	oort	Detai	ls:
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Case Number: 213524 Seq: 1 Gender: F

Reported: 17/11/2005 Weight: 0.00 Hospitalisation: Age: 43

Onset Date: 02/04/2005 **DOB**: 23/08/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.			
Aripiprazole (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 17/03/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
17/11/2005	Sodium		02/04/2005	142	
17/11/2005	White blood cells		02/04/2005	9.0	
17/11/2005	White blood cells		04/04/2005	6.8	
17/11/2005	White blood cells		11/04/2005	6.0	

Additional Information:

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Case Number: 213577

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Reported: 18/11/2005		Weight: 0.00					
lospitalisation:				Age: 99u			
Onset Date:		DOB:					
Outcome: Recovered			C	ausality: Causality possible			
eaction Details: Preferred Term	Coverity	Donor	t Description	Tractment			
Akathisia	Severity	•	t Description	Treatment			
ıkdulisid		being treated with	oped akathisia whi Aripiprazole.	le Aripiprazole, Tramadol and Benzodiazepines were ceased.			
Medicine Details: TRAMAL (Suspected)		Reaso	on:				
Batch:	Started:		Stopped:				
Benzodiazepine NOS (Suspected)	otal tou.	Reaso					
,							
Batch:	Started:		Stopped:				
Abilify (Suspected)		Reaso	on: Unspecified so	hizophrenia			
Tablet	10.0	Milligram I	Daily	Oral			
Batch:	Started:		Stopped:	29/10/2005			
_aboratory Investigation	1S: Range Date Test	ed Result		Details			
Additional Information:							
oort Run: 01/06/2007 01:53PM	Database: pusime02	AD	RS004	Page 159 of 220			



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
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Case Number:214003Seq: 1Gender:UReported:05/12/2005Weight:83.00Hospitalisation:Required a visit to the doctorAge: 42

Onset Date: 15/05/2005 Age: 42

DOB: 10/05/1963

Outcome: Recovered 15/08/2005 Causality: Causality probable

Reaction Details:

eaction Details.							
Preferred Term	Severity	Report Description	Treatment				
Akathisia		The patient developed akathisia and inner restlessness, tongue and buccal movements, teeth chattering and vocal ties.	Changed to Seroquel 300mg bd.				
Restlessness							

Medicine Details:

Abilify (Suspected)

Tablet

30.0 Milligram

Daily

Oral

Batch:

Started: 16/03/2005

Stopped: 08/07/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 160 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 214148
 Seq:
 1
 Gender:
 M

 Reported:
 08/12/2005
 Weight:
 0.00

Hospitalisation: Hospitalisation prolonged Age: 25

Onset Date: 25/10/2005 **DOB**: 05/07/1980

Outcome: Recovered 05/11/2005 Causality: Causality probable

Reaction Details:

todotion botanor			
Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient developed akathisia.	

Medicine Details:

Abilify (Suspected) Reason:

Tablet 15.0 Milligram Daily Oral

Batch: Started: 14/10/2005 Stopped: 25/10/2005

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Previous reaction to Resperidone.

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Case Number: 214329

Reported: 15/12/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Hospitalisat	tion: Admitted t	o hospital	Age: 99U				
Onset D	Date: 27/11/200	5	DOB:				
Outco	ome: Unknown		Causality: Causality possible				
Reaction E	Details:						
Pr	eferred Term	Severity	Repo	ort Description	Treatment	:	
Blood press	sure increased	Caused or prolonged inpatient hospitalisation	an allergic react Abilify, her symp blood pressure (ted that she experienced ion after starting oral stoms were increased BP was 204), agitation, ion, nausea and sweating.			
Agitation		Caused or prolonged inpatient hospitalisation					
<u>Medicine</u>							
Abilify (Sus	•		Rea	son:			
Tabl	et			Oral			
Bate	cn:	Started: 17/	11/2005	Stopped:			
Laborato	rv Investigat	ions:					
Date	Туре		ed Result	D	etails		
Date Type Range Date Tested Result Details Additional Information:							
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Case Number: 214329

Reported: 15/12/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F **Weight:** 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Hospitalisation: Admitted to h	ospital	Age : 99U				
Onset Date: 27/11/2005		DOB:				
Outcome: Unknown		Causality: Causality possible				
Reaction Details:	,					
Preferred Term	Severity	Report Description	Treatment			
Anxiety	Caused or prolonged inpatient hospitalisation					
Dyspepsia	Caused or prolonged inpatient hospitalisation					
Hyperhidrosis	Caused or prolonged inpatient hospitalisation					
Medicine Details:						
Abilify (Suspected)		Reason:				
Tablet		Oral				
Batch:	Started: 17/11/200	5 Stopped:				
Laboratory Investigation	ns:					
Additional Information:						
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Case Number: 214329

Reported: 15/12/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Hospitalisation: Admitted to hos	spital	Age : 99U				
Onset Date: 27/11/2005		DOB:				
Outcome: Unknown		Causality: Causality possible				
Reaction Details:	1 -					
Preferred Term	Severity	Report Description	Treatment			
Nausea	Caused or prolonged inpatient hospitalisation					
Medicine Details: Abilify (Suspected)		Reason:				
Tablet		Oral				
Batch:	Started: 17/11/2005	Stopped:				
Laboratory Investigations	:					
Additional Information:						
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Hospitalisation:

Case Number: 214403

Reported: 19/12/2005

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M Weight: 0.00

Age: 99u

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Onset Date: DOB:								
Outcome: Unknown		Causality: Causality possible						
Reaction Details:								
Preferred Term	Severity	Repo	ort Descriptio	n	Treatmen	t		
Insomnia	The patient experienced insomnia, agitation and he had stabbed himself in the neck while receiving Aripiprazole.			Benzodiazepines.				
Agitation	Caused or prolonged inpatient hospitalisation							
Self mutilation	Caused or prolonged inpatient hospitalisation							
Medicine Details:								
Abilify (Suspected)			son:					
Tablet Batch:	15.0 Started:	Milligram	Daily	Oral oped:				
Laboratory Investigati		.1						
Date Type	Range Date Leste	ed Result		D	etails			
Additional Information	Date Type Range Date Tested Result Details Additional Information:							
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

: 04/01/200		1			Gender:	IVI	
. 04/01/200)6				Weight:	0.00	
:					Age:	19	
: 10/11/200)5				DOB:	13/05/1986	
Not yet re	covered			(Causality:	Causality poss	ible
ils:							
red Term	Se	verity	Repo	rt Description		Treatmer	nt
		cha	anges on the f	ace, physician dia	d motor gnosed		
			Poss	on: Unenocified r	ourosis		
a)		15 O Mill					
	C+.			-			
nvestigat							
nvestigat Type	ions: Range	Date Tested	Result		Detail	S	
	tails:	tails:	tails: tails: 15.0 Mills:	red Term Severity Repo Patient developer changes on the fathese symptoms tails: d) Reas	red Term Severity Patient developed neck cramps and changes on the face, physician diag these symptoms as Bell's palsey. tails: d) Reason: Unspecified management of the part of the	red Term Severity Report Description Patient developed neck cramps and motor changes on the face, physician diagnosed these symptoms as Bell's palsey. tails: Reason: Unspecified neurosis 15.0 Milligram Daily Oral	red Term Severity Report Description Treatment Patient developed neck cramps and motor changes on the face, physician diagnosed these symptoms as Bell's palsey. **Table 1 Patient developed neck cramps and motor changes on the face, physician diagnosed these symptoms as Bell's palsey. Patient developed neck cramps and motor changes on the face, physician diagnosed these symptoms as Bell's palsey. Patient developed neck cramps and motor changes on the face, physician diagnosed these symptoms as Bell's palsey. Patient developed neck cramps and motor changes on the face, physician diagnosed these symptoms as Bell's palsey. Patient developed neck cramps and motor changes on the face, physician diagnosed these symptoms as Bell's palsey.

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Case Number: 214712

Reported: 09/01/2006

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Preferred Term Severity Report Description Treat Agitation Caused or prolonged inpatient hospitalisation Reason: Medicine Details: Abilify (Suspected) Reason: Batch: Started: Stopped:	ospitalisation: Admitted to	hospital	A	\ge : 99U			
Preferred Term Severity Report Description Treation of Caused or prolonged inpatient hospitalisation (Caused or prolonged inpatient hospitalisation hospitalisation) Pledicine Details: Abilify (Suspected) Reason: Batch: Started: Stopped: Abilify (Suspected) Reason: Batch: Started: Stopped:			DOB: Causality: Causality possible				
Preferred Term							
Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient Caused or prolonged inpatien		Severity	Papart Description	Treatment			
Medicine Details: Abilify (Suspected) Batch: Started: Stopped: -aboratory Investigations: Date Type Range Date Tested Result Details	Agitation	Caused or prolonged inpatient	Patient experienced agitation which was quite bad and then she took an Abilify	Abilify was withdrawn.			
Abilify (Suspected) Batch: Started: Stopped: -aboratory Investigations: Date Type Range Date Tested Result Details	Overdose	prolonged inpatient					
Batch: Started: Stopped: _aboratory Investigations: Date Type Range Date Tested Result Details	Medicine Details:						
_aboratory Investigations: Date Type Range Date Tested Result Details	Abilify (Suspected)		Reason:				
_aboratory Investigations: Date Type Range Date Tested Result Details	Ratch:	Started:	Stonned:				
Date Type Range Date Tested Result Details Additional Information:							
			d I Danish I	Dataila			
Additional Information:	Date Type	Range Date Lester	d Result	Details			
	Additional Information	:					
eport Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page	nort Run : 01/06/2007 - 01:53PM	Database: nusime02	ADRS004	Page 167 of 220			



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 214746 Reported: 09/01/2006 ospitalisation: Onset Date: Outcome: Not yet recovered	Seq: 1					
	ed.	Gender: F Weight: 64.00 Age: 40 DOB: 31/07/1965				
oction Dotaile:	eu		Causanty	: Causality possible		
action Details: Preferred Term	Severity	Reno	ort Description	Treatment		
ongenital cardiovascular anoma	ly	Neonate has car	diac defect requiring			
ug exposure during pregnancy		surgery.				
edicine Details: Aripiprazole (Suspected) Tablet	15.0	Rea s Milligram	son: Unspecified psychosis Daily Oral			
Batch:	Started:		Stopped:			
.aboratory Investigations:	: Inge Date Teste	ed Result	Deta	nils		
Date Type Ra	nge Date Leste	ed Result	Deta	alls		
Additional Information:						

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

ils:							
: 214785	Sea	ı: 1				Gender:	M
						_	
	5					_	
					(Causality possible
	u					ausunty.	Oddsanty possible
	9	everity		Penort De	ecription		Treatment
			CLICDECT		· ·	o hava	Heatinent
iignant syndi	ome		SUSPECTED - Patient was noted to have increasing creatine phosphokinase level which may be due to muscle wasting and "possibly" a " sign of neuroleptic malignant syndrome " while receiving Aripiprazole.				
ohosphokina	se incr						
YDROBROMID	E (Other drug)			Reason:	Depression		
		20.0	Milligram	Daily		Oral	
	,	Started: 31/0	8/2001		Stopped:		
ed)				Reason:			
		15.0	Milligram	Daily		Oral	
	;	Started:			Stopped:		
		Date Teste	od Res	ult		Deta	ile
ı yp c	range	Date 16816	nes	uit		שבומ	iio
nformatio	n:	•	•	1			
	etails: Type	e: 214785 Sequence 10/01/2006: : 15/11/2005: Recovered ails: rred Term Sequence 10 Sequenc	r: 214785 Seq: 1 l: 10/01/2006 : p: 15/11/2005 : Recovered ails: rred Term Severity lignant syndrome phosphokinase incr 20.0 Started: 31/0 ed) 15.0 Started:	: 214785 Seq: 1 I: 10/01/2006 : I: 15/11/2005 : Recovered Suspection Suspect	: 214785 Seq: 1 :: 10/01/2006 :: 15/11/2005 :: Recovered ails: rred Term Severity Report De lignant syndrome SUSPECTED - Patient increasing creatine phrosphokinase incr Stails: PYDROBROMIDE (Other drug) Reason: 20.0 Milligram Daily Started: 31/08/2001 Reason: 15.0 Milligram Daily Started: Started: Start	: 214785 Seq: 1 :: 10/01/2006 :: :: 15/11/2005 :: Recovered	table to the state of the state

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 215937 Seq: 1 Gender: F

Reported: 16/02/2006 Weight: 91.00 Hospitalisation: Age: 29

Onset Date: 15/11/2005 **DOB:** 12/05/1976

Outcome: Recovered 20/12/2005 Causality: Causality possible

Reaction Details:

100.01.01				
	Preferred Term	Severity	Report Description	Treatment
Dyskines	ia			Abilify was ceased, Efexor XR was reduced to 150mg.

Medicine Details:

Medicine Details.				
Abilify (Suspected)		Reason: Unspec	ified schizophrenia	
Tablet	30.0 Milligram	Daily	Oral	
Batch:	Started: 27/06/2005	Sto	pped: 29/11/2005	0
EFEXOR-XR (Suspected)		Reason: Unspec	ified schizophrenia	
Capsule	300.0 Milligram	Daily	Oral	
Batch:	Started: 27/06/2005	Sto	pped: 25/07/2005	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 215962 Seq: 1 Gender: M

Reported: 17/02/2006 Weight: 0.00 Hospitalisation: Age: 36

Onset Date: 15/02/2006 **DOB**: 29/08/1969

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
	innatient	80bpm)	Observation and biochemical monitoring. CK slowly resolving. Tachycardia resolved.
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	500.0 Milligram	2 times	Oral
Batch:	Started: 31/01/2006	Stopped:	
CLOPIXOL-ACUPHASE (Suspected)		Reason:	
Injection			Intramuscular
Batch:	Started: 01/02/2006	Stopped:	08/02/2006
Abilify (Suspected)		Reason:	
Tablet	30.0 Milligram	1 time	Oral
Batch:	Started: 25/01/2006	Stopped:	15/02/2006

Laboratory Investigations:

	j mroonganone:					
Date	Туре	Range	Date Tested	Result	Details	
	Creatine kinase				14/02/2006 CK - 282 15/02/2006 CK - 263	

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	oort	Detai	ls:
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Case Number: 216020 Seq: 1 Gender: F

Reported: 20/02/2006 Weight: 70.00 Hospitalisation: Age: 29

Onset Date: 04/02/2006 **DOB**: 08/04/1976

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botanoi			
	Preferred Term	Severity	Report Description	Treatment
	Hyperglycaemia		Patient experienced hyperglycaemia.	

Medicine Details:

INSULIN NOS (Other drug) Reason: Diabetes mellitus

34.0 Unit

Batch: Started: Stopped: 0

NOVORAPID (Other drug) Reason: Diabetes mellitus

46.0 Unit

Batch: Started: Stopped:

Aripiprazole (Suspected) Reason: Unspecified psychosis

Tablet 15.0 Milligram Daily Oral

Batch: Started: 03/02/2006 **Stopped:** 14/02/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

eport Details: Case Number: 216204 Reported: 28/02/200	Seq : 1			der: M ght: 0.00
ospitalisation:				.ge: 73Y
Onset Date:				OB:
Outcome: Recovere	ed		Causa	lity: Causality probable
eaction Details: Preferred Term	Soverity	Donort D	escription	Treatment
Grand mal convulsion	Severity	Patient developed gra	•	Abilify was stopped
	I	r august agreen		r some otopped
Medicine Details: EFEXOR (Other drug)		Reason:		
Batch:	150.0 Started:	Milligram	Oral Stopped:	
Abilify (Suspected)	Starteu.	Reason:	Depression	
Tablet	5.0	Milligram Daily		
Batch:	Started:		Stopped:	0
_aboratory Investigat	tions: Range Date Test	ted Result		Details

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 216287	Seq: 1		Gender	: F
Reported: 07/03/2006			Weight:	0.00
espitalisation:			Age:	34Y
Onset Date:			DOB	
Outcome: Death, maybe	drug		Causality	: Causality possible
action Details:				
Preferred Term	Severity	Report Desc	ription	Treatment
eath	Death	Patient was found dead.		
edicine Details:				
Abilify (Suspected)		Reason:		
Tablet			Oral	
Batch:	0441-		Stopped:	
Dalcii.	Started:		Otoppea.	
	Started:	Reason:	оторреи.	
CLOZAPINE (Suspected)		Reason:		
	Started:	Reason:	Stopped:	
CLOZAPINE (Suspected)		Reason:		
CLOZAPINE (Suspected)		Reason:		
CLOZAPINE (Suspected)		Reason:		
CLOZAPINE (Suspected)		Reason:		
CLOZAPINE (Suspected) Batch:	Started:	Reason:		
Batch: Batch: Aboratory Investigation	Started:		Stopped:	
Batch: Batch:	Started:			ils
Batch: Batch: aboratory Investigation	Started:		Stopped:	ils
Batch: Batch: aboratory Investigation	Started:		Stopped:	ils
Batch: Batch: aboratory Investigation	Started:		Stopped:	ills
Batch: Batch: aboratory Investigation	Started:		Stopped:	ils
Batch: Batch: aboratory Investigation	Started:		Stopped:	ils
Batch: Batch: aboratory Investigation	Started:		Stopped:	ills
Batch: Batch: aboratory Investigation Date Type	Started:		Stopped:	ils
Batch: Batch: aboratory Investigation	Started:		Stopped:	ills
Batch: Batch: Aboratory Investigation Date Type	Started:		Stopped:	ills
Batch: Batch: aboratory Investigation Date Type	Started:		Stopped:	ils

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 216564 Seq: 1 Gender: M
Reported: 16/03/2006 Weight: 0.00
Hospitalisation: Age: 25

Onset Date: 15/04/2005 **DOB:** 02/10/1979

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Complaining of involuntary movements of shoulder and upper chest, described as a flicking movement while he is falling asleep-> wakes him up-consistent with myclonic jerks.	
Myoclonus			

Medicine Details:

BENZTROPINE MESYLATE (Other drug) Reason:

1.5 Milligram

Batch: Started: Stopped:

Aripiprazole (Suspected) Reason: Unspecified psychosis

Tablet 1.0 Dose Unspecified Daily Oral

Batch: Started: 15/04/2005 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Describes sereve side effects fromprevious antipsychotics, eg Quetiapine, Olanzapine and Risperidone.

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Case Number: 217292

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Reported: 11/04/2006				Weigl	ht: 0.00	
lospitalisation:			Age: 17Y			
Onset Date:			DOB:			
Outcome: Unknown			Causality: Causality possible			
eaction Details:					T	
Preferred Term	Seve			ort Description	Treatment	
Neuroleptic malignant syndro	me	Pa syr	tient developendrome.	ed neuroleptic malignant		
Medicine Details: Abilify (Suspected)			Rea	son:		
Ability (Suspected)			Rea	SOII.		
Batch:	Star	ted:		Stopped:		
_aboratory Investigatio	ons:					
Date Type		ate Tested	Result	D	etails	
Additional Information: The patient was also taking mult		ed) antipsyc	chotic agents.			
port Run : 01/06/2007	Databaso: nucir		Λ	DR\$004	Dago 176 of 220	

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 217497 Seq: 1 Gender: M

Reported: 19/04/2006 Weight: 0.00 Hospitalisation: Age: 30

Onset Date: DOB: 12/09/1975

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	toaction Dotaile			
	Preferred Term	Severity	Report Description	Treatment
	Erectile dysfunction		Patient developed marked sexual side effects, particularly impotence.	Ceased Abilify.
	Erectile dysfunction			

Medicine Details:

Abilify (Suspected) Reason: Unspecified schizophrenia

Tablet 15.0 Milligram Daily Oral

Batch: **Started**: 15/06/2005 **Stopped**: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Breast mass while on Risperidone and sedation while on Quetiapine.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

case Number. 217049	Seq. 1		Gend	iei. r		
Reported: 24/04/2006			Weight: 0.00			
spitalisation:				ge: 99u		
Onset Date:			DOB:			
Outcome: Not yet recov	vered		Causal	ity: Causality possible		
ection Details:						
Preferred Term	Severity	Rep	ort Description	Treatment		
ug ineffective	Caused or prolonged inpatient hospitalisation	Patient experier being treated w	nced a lack of effect while ith Abilify.	5 months in an acute psychiatric unit.		
edicine Details: OLOFT (Suspected)		Rea	ason:			
Tablet			Oral			
Batch:	Started:		Stopped:			
OZAPINE (Suspected)		Rea	ason:			
Tablet			Oral			
Batch:	Started:		Stopped:			
oilify (Suspected)		Rea	eason: Unspecified schizophrenia			
Tablet	30.0	Milligram	Daily Oral			
Batch:	Started:		Stopped:			
aboratory Investigation Date Type	ns: Range Date Teste	ed Result		Details		
dditional Information:						
ort Run: 01/06/2007 01:53PM	Database: pusime02	,	ADRS004	Page 178 of 220		



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 217993 Seq: 1 Gender: F

Reported: 04/05/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 19

Onset Date: 30/03/2004 **DOB**: 15/07/1984

Outcome: Recovered 01/04/2004 **Causality:** Causality probable

Reaction Details:

caction betails.							
Preferred Term	Severity	Report Description	Treatment				
Agitation	Life threatening	Agitation due to increase of Aripiprazole from 15mg on 17/3 to 30mg.	Aripiprazole ceased.				
Therapy regimen changed	Life threatening						

Medicine Details:

Aripiprazole (Suspected) Reason:

Tablet 30.0 Milligram Daily Oral

Batch: Started: 24/03/2004 Stopped: 29/03/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report 217991 is the first sequence to this report.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 218522
 Seq: 1
 Gender: M

 Reported:
 19/05/2006
 Weight:
 70.00

Hospitalisation: Treated in outpatient department only.

Onset Date: 30/03/2006

Age: 30

DOB: 13/09/1975

Outcome: Recovered Causality: Causality probable

Reaction Details:

edotion betailer						
Preferred Term	Severity	Report Description	Treatment			
	prolonged inpatient hospitalisation		Aripiprazole and Escitalopram withheld.			

Medicine Details:

Medicine Details.				
Escitalopram (Suspected)		Reason: Depression	า	
Tablet	20.0 Milligram	Daily	Oral	
Batch:	Started: 15/03/2006	Stoppe	ed: 15/03/2006	0
Aripiprazole (Suspected)		Reason: Unspecifie	d schizophrenia	
Tablet	20.0 Milligram	Daily	Oral	
Batch:	Started: 15/03/2006	Stoppe	ed: 15/03/2006	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had comprimised renal function and received Lithium after withheld of the Aripiprazole and Escitalopram.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

y Pateint of function	Report Desc experienced wild tests.	Ago DO Causalit	t: 0.00 e: 99u
Pateint e function	experienced wild tests.	Age DO Causalit	e: 99u B: y: Causality possible
Pateint e function	experienced wild tests.	Age DO Causalit	e: 99u B: y: Causality possible
Pateint e function	experienced wild tests.	DO Causalit	B: y: Causality possible
Pateint e function	experienced wild tests.	Causalit	y: Causality possible
Pateint e function	experienced wild tests.	cription	
Pateint e function	experienced wild tests.		Treatment
Pateint e function	experienced wild tests.		Treatment
function	tests.	lly abnormal liver	
30.0 Milligram	Reason:		
30.0 Milligram	Reason:		
30.0 Milligram			
· ·	Daily	Oral	
:	,	Stopped:	
Tostod	Pocult	Do	staile
rested K	Result	De	ctalis
,	Tested F	Tested Result	Tested Result De



Case Number: 218592

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Reported: 23/05/2006		Wei	ght: 0.00			
ospitalisation:		A	Age: 99u			
Onset Date:		D	OB:			
Outcome: Unknown		Causality: Causality possible				
eaction Details:	- T					
Preferred Term	Severity	Report Description	Treatment			
Pancreatitis	Caused or prolonged inpatient hospitalisation	Pateint was hospitalised with pancreatitis while receiving Aripiprazole.	Aripiprazole withdrawn.			
Medicine Details: Abilify (Suspected)		Reason:				
Tablet		Oral				
Batch:	Started:	Stopped:				
aboratory Investigations		.1 1				
Date Type Ra	inge Date Teste	ed Result	Details			
	1					
Additional Information:						



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 219054
 Seq: 1
 Gender: M

 Reported:
 07/06/2006
 Weight:
 92.30

 Hospitalisation:
 Age: 43

Onset Date: 05/01/2006 **DOB**: 31/05/1962

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Increased dosage of Aripiprazole (15mg daily to 30mg daily), patient felt like he was "speeding". Amputated finger due to command hallucinations. Non-compliant with Olanzapine for 4 days. Possible worsening of psychosis (hallucinations) due to Aripiprazole.	Withdrawal of Aripiprazole.
Hallucination			
Self mutilation			

Medicine Details:

Aripiprazole (Suspected)		Reason:	Unspecified schizophrenia
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 14/12/2005		Stopped: 06/01/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 219223 Seq: 1 Gender: F

Reported: 19/06/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 99u
Onset Date: 15/05/2006 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cyanosis	prolonged inpatient hospitalisation	Patient developed cyanosis, decreased exercise tolerance, symptoms of cardiac dysfunction, pedal edema, breathlessness, and suspected inappropriate secreation of dntidiuretic hormone. About six weeks afte the start of therapy, the Aripipraxole daily dose was increased from 5mg to 10mg, which is when the events began.	
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected) Reason: Unspecified schizophrenia

Tablet 10.0 Milligram Daily Oral

Batch: Started: 15/03/2006 Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

History of Prader-Willi syndrome.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Reported: 19/06/2006 Hospitalisation: Admitted to hospital Onset Date: 15/05/2006 Outcome: Unknown Leaction Details:	I		Weight: Age: DOB:	99u
Onset Date: 15/05/2006 Outcome: Unknown eaction Details:	I			
Outcome: Unknown eaction Details:			DOB:	
eaction Details:				
			Causality:	Causality possible
Drafarrad Tarra				
Preferred Term	Severity	Report Des	scription	Treatment
proint	aused or olonged patient ospitalisation			
ling	aused or rolonged patient ospitalisation			
pro inp	aused or olonged patient ospitalisation			
Medicine Details:				
Abilify (Suspected)		Reason:	Unspecified schizophrenia	l
Tablet	10.0 Mil	lligram Daily	Oral	
Batch:	Started: 15/03/2	2006	Stopped:	

Additional Information:

Laboratory Investigations:

History of Prader-Willi syndrome.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	ort D)etai	ls:
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Case Number:219223Seq: 1Gender:FReported:19/06/2006Weight:0.00Hospitalisation:Admitted to hospitalAge: 99u

Onset Date: 15/05/2006 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion botanor			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)

Tablet

Batch:

Reason: Unspecified schizophrenia

Daily

Oral

Stopped:

Laboratory Investigations:

Additional Information:

History of Prader-Willi syndrome.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
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Case Number: 219323 Seq: 1 Gender: F

Reported: 20/06/2006 Weight: 69.00 Hospitalisation: Required a visit to the doctor Age: 58

Onset Date: 13/04/2006 **DOB**: 23/05/1947

Outcome: Unknown Causality: Causality possible

Reaction Details:

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Low density lipoprotein increased		Rise in LDL level when swiched from Olazapine to Abilify.	Nil.

Medicine Details:

ATORVASTATIN (Other drug)		Reason:	Othr&unspec metabolic diseases	
Tablet	40.0 Milligram		Oral	
Batch:	Started: 15/05/2005		Stopped:	
EFEXOR-XR (Other drug)		Reason:	Depression	
Capsule, modified release	300.0 Milligram		Oral	
Batch:	Started:		Stopped:	
Abilify (Suspected)		Reason:	Manic depressive psycho, depre	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 10/04/2006		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 219616				
	Seq: 1			der: M
Reported: 03/07/200	6			ght: 0.00
ospitalisation:				Age: 33
Onset Date:	.1			OOB: 22/12/1972
Outcome: Recovered	a		Causa	ality: Causality possible
eaction Details: Preferred Term	Coverity	Dan	ant Decemention	Transferent
Convulsive threshold lowere	Severity		ort Description	Treatment
John Valsive (Heshold lowere	eu	seizure threshol	nced a decrease in the d.	
Medicine Details: CARBAMAZEPINE (Other drug))	Rea	son: Convulsions	
D-4-b-	Started:		.	
Batch:	Starteu.		Stopped:	
Batch: Abilify (Suspected)	Starteu.	Rea	stopped: uson: Unspecified psychological	sis
		Rea	Daily Unspecified psychos	sis
Abilify (Suspected)	30		son: Unspecified psychos	sis 0
Abilify (Suspected) Tablet	30 Started:	0.0 Milligram	Daily Unspecified psychos	

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Patient had psychotic s	Report Desc d suffered an ir state with an in allucinations ar Reason:	Cause cription increasingly increase in his	nder: M ight: 0.00 Age: 34Y DOB: ality: Causality possible Treatment Abilify discontinued.		
Patient had psychotic sauditory ha ideation.	d suffered an ir state with an in allucinations ar	Cause cription creasingly ncrease in his	Age: 34Y DOB: ality: Causality possible Treatment		
Patient had psychotic sauditory ha ideation.	d suffered an ir state with an in allucinations ar	Cause cription increasingly ncrease in his	DOB: ality: Causality possible Treatment		
Patient had psychotic sauditory ha ideation.	d suffered an ir state with an in allucinations ar	cription increasingly increase in his	ality: Causality possible Treatment		
Patient had psychotic sauditory ha ideation.	d suffered an ir state with an in allucinations ar	cription increasingly	Treatment		
Patient had psychotic sauditory ha ideation.	d suffered an ir state with an in allucinations ar	ncreasingly ncrease in his			
Patient had psychotic sauditory ha ideation.	d suffered an ir state with an in allucinations ar	ncreasingly ncrease in his			
psychotic s auditory ha ideation.	state with an in allucinations ar	ncrease in his	Ability discontinued.		
Started:					
Started:					
Started:	Daily	Reason:			
Started:	Daily	Oral	I		
	•	Stopped:	0		
Date Tested Resu			Details		
Date Tested Resu	sult				
	Starteu.	Starteu.	Зтаптец.		

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rei	port	Detai	ls:
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 Case Number:
 219844
 Seq: 1
 Gender:
 M

 Reported:
 10/07/2006
 Weight:
 0.00

 Hospitalisation:
 Age: 34Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	todotion Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Dilatation ventricular		Patient had shown a dilated left ventricle with mild to moderate left ventricular systolic dysfunction.	Abilify discontinued
	Ventricular dysfunction			

Medicine Details:

Medicine Details.				
Abilify (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:		Stopped:	
CLOZARIL (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	650.0 N	Milligram Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: Chronic paranoid shizophrenia, anxiety, depression, smoker and overweight.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Repo	\rt	Doto	ile
Rebu	JIL	Deta	IIIS:

 Case Number:
 220455
 Seq: 1
 Gender: M

 Reported:
 31/07/2006
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 19

Onset Date: 18/11/2004 **DOB**: 20/07/1985

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botanor			
Preferred Term	Severity	Report Description	Treatment
Somnolence		Patient stopped Abilify because of drowsiness.	

Medicine Details:

CANNABIS PREPARATION (Oti	ner drug)	Reason:		
Batch:	Started:	Sto	ppped:	
DEXAMPHETAMINE SULPHATE	(Other drug)	Reason:		
Batch:	Started:	Sto	opped:	
Abilify (Suspected)		Reason: Unspe	cified psychosis	
Tablet	15.0 Milligram	Daily	Oral	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Neurologist Diagnosis: Autistic spectrum disorder and iatrogenic Tardive Dyskinesia. Reduced IQ secondary to birth hypoxia (mild intellectual impairment).

Report 220456 is the second sequence to this report and 220457 is the third sequence.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 220457 Seq: 1 Gender: M

Reported: 31/07/2006 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 20

Onset Date: 06/09/2005 **DOB**: 20/07/1985

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	prolonged inpatient hospitalisation		Quetiapine, Propranolol, Lorazepam 1mg tds for 2 days,

Medicine Details:

Abilify (Suspected)	Ī	Reason: Uns	pecified psychosis	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 25/03/2004	\$	Stopped: 30/09/2005	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Neurologist Diagnosis: Autistic spectrum disorder and iatrogenic Tardis Dyskinesia. Reduced IQ secondary to birth hypoxia (mild intellectual impairment).

Report 220455 is the first sequence to this report and 220456 the second sequence.

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 192 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 220457
 Seq: 1
 Gender: M

 Reported:
 31/07/2006
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 20
Onset Date: 06/09/2005 DOB: 20/07/1985

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression	Caused or prolonged inpatient hospitalisation		
Agitation	Caused or prolonged inpatient hospitalisation		
Akathisia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)		Reason:	Unspecified psychosis	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 25/03/2004		Stopped: 30/09/2005	

Laboratory Investigations:

Additional Information:

Neurologist Diagnosis: Autistic spectrum disorder and iatrogenic Tardis Dyskinesia. Reduced IQ secondary to birth hypoxia (mild intellectual impairment).

Report 220455 is the first sequence to this report and 220456 the second sequence.

Report Run: 01/06/2007 01:53PM Database: pusime02 ADRS004 Page 193 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 220457
 Seq: 1
 Gender: M

 Reported:
 31/07/2006
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 20

Onset Date: 06/09/2005 **DOB**: 20/07/1985

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chorea	Caused or prolonged inpatient hospitalisation		
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	R	teason: Un	specified psychosis
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 25/03/2004		Stopped: 30/09/2005

Laboratory Investigations:

Additional Information:

Neurologist Diagnosis: Autistic spectrum disorder and iatrogenic Tardis Dyskinesia. Reduced IQ secondary to birth hypoxia (mild intellectual impairment).

Report 220455 is the first sequence to this report and 220456 the second sequence.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls	:
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Case Number: 220752 Seq: 1 Gender: F

Reported: 14/08/2006 Weight: 55.00 Hospitalisation: Age: 39

Onset Date: 10/06/2006 **DOB**: 20/04/1967

Outcome: Recovered 06/07/2006 Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	threatening	Hypertonia in all limbs, frequent and small amount urine, temp 37.8C, decreased speech - almost mute and possible neuroleptic malignant syndrome.	
Body temperature increased	Life threatening		
Hypertonia	Life threatening		
Neuroleptic malignant syndrome	Life threatening		
Pollakiuria	Life threatening		

Medicine Details:

Aripiprazole (Suspected) Reason: Unspecified psychosis

Tablet 15.0 Milligram Daily Oral

Batch: Started: 19/05/2006 Stopped: 10/06/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
14/08/2006	Creatine				Increased CK to 900.

Additional Information:

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Case Number: 222427

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Reported: 13/10/2006			Weight:	0.00
ospitalisation:			Age:	99u
Onset Date:			DOB:	
Outcome: Not yet recove	red		Causality:	Causality possible
eaction Details:	T 0 "	T 5 (5) ::		+ , ,
Preferred Term	Severity	Report Description		Treatment
/ision blurred		Eye problems (focus is off, hard whole picture, kind of get stuck a muscles might be stiff), stomach chest pains.	to see the and pains and	
Abdominal pain upper				
Chest pain				
Medicine Details: Abilify (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:	Stopp	ed:	
_aboratory Investigations Date Type F	Range Date Tes	red Result	Detai	'e
Date Type 1	tange Date res	ica result	Detail	3
	·			
Additional Information:				



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number:	222500	Seq: 1			Gende	er: M	
Reported:	16/10/2006	i			Weigh	t: 0.00	
spitalisation:						e: 99u	
Onset Date:					DO	В:	
Outcome:	Unknown				Causalit	y: Causality poss	ible
action Deta	ils:						
Preferr	ed Term	Severity	F	Report Desc	ription	Treatmer	nt
abetes mellitus	S		Diabetes me	ellitus.			
edicine Det bilify (Suspected Tablet				Reason:	Oral		
Batch:		Started:	.0 Milligram	Daily	Stopped:		
b a maka m . Im							
boratory Ir	Type	O ns: Range Date T	ested Result		De	tails	
Date	Турс	range Date 1	Colcu Meduli			tans	
dditional In	formation	:					
ort Run:01/06/20	07 01:53PM	Database: pusime02		ADRS004		Page 197	of 220



Case Number: 223733

Reported: 04/12/2006

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Hospitalisation: Onset Date: Outcome: Unknown				Age : 99u				
				DOB: Causality: Causality possible				
eaction De						Causaii	ity. Causanty po-	SSIDIC
	ferred Term	Seve	rity	Repo	rt Descripti	on	Treatm	ent
eeling of de			Pat	ient had feelir bression, akat	ngs of despa			
Akathisia				,				
epression								
Medicine [Details:							
SEROQUEL (S				Reas	on:			
Batch		Start	ed:			opped:		
Abilify (Suspe			45.0 M:U:	Reas		cified schizophr	enia	
Tablet Batch		Start	45.0 Milli	gram	Daily	Oral opped:		
	/ Investigati		-4- T4-4	Desult) o to ilo	
Date	Туре	Range Da	ate Tested	Result		L	etails	
Additional	Information	:						
port Run: 01/0	6/2007 01:53PM	Database: pusin	ne02	A	DRS004		Page 19	8 of 220



Case Number: 223788

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Reported: 05/12/2006			Weigh	t: 101.00	
ospitalisation:			Age	e : 43	
Onset Date:				3 : 25/04/1963	
Outcome: Unknown			Causalit	y: Causality possi	ble
eaction Details:	- 	D. (D.)	I	- -	
Preferred Term	Severity	Report Descrip	i	Treatmen	[
Akathisia	threatening	Previously taken oral risper tolerated well, howevere, do been given before. Patient akathesic with aripiprazole.	epot had never became		
Medicine Details: Aripiprazole (Suspected)		Reason:			
Tablet			Oral		
Batch:	Started:	•	Stopped:		
aboratory Invostigation	ne:				
aboratory Investigation Date Type	Range Date Teste	ed Result	De	tails	
Julio Typo	rango Dato Foot	, a result			
Additional Information:					
port Run: 01/06/2007 01:53PM	Database: pusime02	ADRS004		Page 199	of 22



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report	Detail	s:
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 Case Number:
 224201
 Seq: 1
 Gender: M

 Reported:
 19/12/2006
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 70Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

toaction Botano.			
Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Life threatening	Cardiac arrest.	

Medicine Details:

Medicine Details.					
RISPERIDONE (Suspected)			Reason:		
Batch:	Started:			Stopped:	
Abilify (Suspected)			Reason:		
Tablet	10.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Prior to the start of the aripiprazole therapy, the patient was admitted to the hospital while receiving risperidone. He was then switched to aripiprazole 10mg, and within 24 hours had experienced cardiac arrest. Medical history: included cardiovascular disease.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 224753
 Seq: 1
 Gender:
 F

 Reported:
 17/01/2007
 Weight:
 0.00

Hospitalisation: Required a visit to the doctor **Age**: 37

Onset Date: 06/12/2006 DOB: 20/08/1969
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Nausea		Nausea, vomiting and facial rash.	Moxolon and phenergan.
Urticaria			
Vomiting			

Medicine Details:

Abilify (Suspected)

Tablet

10.0 Milligram

Daily

Oral

Batch:

Started: 06/12/2006

Stopped: 06/12/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 224786 Seq: 1 Gender: F
Reported: 17/01/2007 Weight: 0.00

Hospitalisation: Required a visit to the doctor **Onset Date**: 05/12/2006 **Age**: 37 **DOB**: 20/08/1969

Outcome: Not yet recovered Causality: Causality probable

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain		Two hours after intergestion developed abdominal pain, nausea, vomiting, skin rashes at the face and neck.	
Nausea			
Rash			
Vomiting			

Medicine Details:

Aripiprazole (Suspected)

Tablet

10.0 Milligram

Daily

Oral

Batch: Started: 05/12/2006

Stopped: 05/12/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 01:54PM Database: pusime02 ADRS004 Page 202 of 220



Hospitalisation:

Onset Date:

Case Number: 224812

Reported: 18/01/2007

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

DOB:

Age: 99u

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

eaction Details: Preferred Term			Causality: Causality possible			
Preterred Term		<u> </u>	_			
	Severity	Report Description	Treatment			
luscular weakness	Caused or prolonged inpatient hospitalisation	Patient experienced weakness in her legs, an inability to walk, difficulty with words and stumbling.				
ysphasia	Caused or prolonged inpatient hospitalisation					
ysuria	Caused or prolonged inpatient hospitalisation					
ledicine Details:						
Abilify (Suspected)		Reason:				
Batch:	Started:	Stopped:				
aboratory Investigatio	ons:					
.aboratory Investigation Date Type	O ns: Range Date Tes	ted Result Deta	ails			
	Range Date Test	ted Result Deta	ails			



Case Number: 224812

Reported: 18/01/2007

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Hospitalisation:		Age: 99u				
Onset Date:		DOB:				
Outcome: Not yet reco	vered	Causa	ality: Causality possible			
Reaction Details: Preferred Term	Coverity	Depart Description	Treatment			
Gait disturbance	Severity Caused or prolonged inpatient hospitalisation	Report Description	Пеашеш			
Medicine Details:						
Abilify (Suspected)		Reason:				
Batch:	Started:	Stopped:				
Laboratory Investigation	ns:					
Additional Information:						
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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Deta	ils:						
Case Number	r: 224834 d: 18/01/200	Seq: 1	Gender: F Weight: 0.00				
Hospitalisation	: Admitted	to hospital	Age: 18Y				
Onset Date	9 :		DOB:				
	: Unknown			Caus	sality: Causality possible		
Reaction Det			T				
	rred Term	Severity		ort Description	Treatment		
Abnormal beha	iviour	Caused or prolonged inpatient hospitalisation	behaviour proble	ems escalated.	Risperidone 1mg was reintroduced but her movement disorder worsened again so risperidone was subsequently discontinued.		
Medicine De			Pos	son:			
Aripiprazole (Su	ispected)		Rea	son:			
Batch:		Started:					
Laboratory	Investigat	ions:					
Date	Type	Range Date Test	ed Result		Details		
Bato	1) 0	range Bate reet	ou Hoodit		Botalio		
Additional Information: Yet to exclude other causes such as bulber nerve problems.							

Report Run: 01/06/2007 01:54PM Database: pusime02 ADRS004 Page 205 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Repor	t De	tail	s:
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 Case Number:
 225099
 Seq: 1
 Gender: M

 Reported:
 25/01/2007
 Weight:
 0.00

Hospitalisation: Age: 21

Onset Date: 02/11/2006 **DOB:** 29/11/1984

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	ability	Patient experienced a severe dystonic reaction while receiving Abilify, patient's creatinine kinase level reached 2800, was not able to walk due to severe cramps, not being able to control movement in hands and feet, swolen tongue and an arched back.	Ceased Abilify, treated with 2mg IM Inject of benztropine.
Blood creatine phosphokinase incr	Incapacity/dis ability		
Muscle spasms	Incapacity/dis ability		
Opisthotonus	Incapacity/dis ability		

Medicine Details:

Abilify (Suspected) Reason: Othr&unspec metabolic diseases

Tablet 15.0 Milligram Daily Oral

Batch: Started: Stopped: 02/11/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
25/01/2007	Creatine				Creatinine Kinase - 2800

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 225099	Seq: 1		Gender	: M
Reported: 25/01/2007			Weight:	0.00
Hospitalisation:			Age:	21
Onset Date: 02/11/2006			DOB	: 29/11/1984
Outcome: Recovered			Causality	: Causality possible
Reaction Details:				
Preferred Term	Severity	Report Description		Treatment
Swollen tongue	Incapacity/dis ability			
Medicine Details: Abilify (Suspected)		Reason: Othr&unspec	: metabolic d	iseases
Tablet	15.0 Mill	ligram Daily	Oral	
Batch:	Started:	Stopped	: 02/11/200	6
Laboratory Investigations	<u>:</u>			
Additional Information:				
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Hospitalisation:

Case Number: 225141

Reported: 29/01/2007

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

Age: 62Y

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Onset Date: 10/11/2006				DOB:			
Outcor	ne: Not yet red	covered		Causality: Causality possible			
eaction De	etails:						
Pre	ferred Term	S	everity	Rep	ort Description	Treatment	
pro inp		prolo inpat	nged	Sinus tachycard neck.	ia, tightness back and	Commenced bisoprolol.	
Back pain		prolo inpat	sed or onged ient italisation				
Neck pain		prolo inpat	sed or onged ient italisation				
Medicine [Details:						
ATORVASTA	TIN (Other drug)			Rea	son:		
			80.0 M	Milligram			
Batch			Started:		Stopped:		
SODIUM VALI	PROATE (Other d	rug)		Rea	son:		
Batch	n:	5	Started:	Stopped:			
FRUSEMIDE (Other drug)			Reason:			
Batch	ո։	5	Started:		Stopped:		
IRBESARTAN	(Other drug)			Rea	son:		
Batch	ı·		Started:		Stopped:		
Datei	1.		Jiai leu.				
aborator	y Investigati	ions:					
Date	Туре	Range	Date Teste	d Result		Details	
			1				
Additional	Information	n:					
oort Run : 01/0	6/2007 01:54PM	Database: p	ousime02		ADRS004	Page 208 of 220	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number:	225141	Seq: 1		Gender:	M
Reported:	29/01/2007			Weight:	0.00
Hospitalisation:				Age:	
Onset Date:	10/11/2006			DOB	
Outcome:	Not yet recovered	t		Causality:	Causality possible
Reaction Detai	ils:				
Medicine Det	ails:				
ASPIRIN (Other dr			Reason:		
Batch:		Started:		Stopped:	
Seretide 500/50 Ad	ccuhaler (Other drug)		Reason:		
Batch:		Started:		Stopped:	
Aripiprazole (Susp	pected)		Reason:		
	pected)	5.0 Milligram	Reason: Daily	Oral	
Aripiprazole (Susp	pected)				6
Aripiprazole (Susp	pected)	5.0 Milligram		Oral	3
Aripiprazole (Susp	pected)	5.0 Milligram		Oral	6
Aripiprazole (Susp	pected)	5.0 Milligram		Oral	5
Aripiprazole (Susp Tablet Batch:		5.0 Milligram		Oral	5
Aripiprazole (Susp Tablet Batch:	nected)	5.0 Milligram		Oral	5
Aripiprazole (Susp Tablet Batch:		5.0 Milligram		Oral	5
Aripiprazole (Susp Tablet Batch:		5.0 Milligram		Oral	6
Aripiprazole (Susp Tablet Batch:		5.0 Milligram		Oral	5
Aripiprazole (Susp Tablet Batch:		5.0 Milligram		Oral	6
Aripiprazole (Susp Tablet Batch:		5.0 Milligram		Oral	5
Aripiprazole (Susp Tablet Batch:		5.0 Milligram		Oral	6
Aripiprazole (Susp Tablet Batch:	ovestigations:	5.0 Milligram		Oral	5
Aripiprazole (Susp Tablet Batch:	ovestigations:	5.0 Milligram		Oral	
Aripiprazole (Susp Tablet Batch:	ovestigations:	5.0 Milligram		Oral	6
Aripiprazole (Susp Tablet Batch:	ovestigations:	5.0 Milligram		Oral	
Aripiprazole (Susp Tablet Batch:	ovestigations:	5.0 Milligram		Oral	
Aripiprazole (Susp Tablet Batch:	ovestigations:	5.0 Milligram		Oral	

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:					
Case Number: 225382	Seq: 1	G	Gender: M		
Reported: 02/02/2007		Weight: 95.00			
lospitalisation: Required a	visit to the doctor		Age: 21		
Onset Date: 04/01/2007		DOB : 18/11/1985			
Outcome: Not yet reco	overed	Cai	usality: Causality possible		
eaction Details:					
Preferred Term	Severity	Report Description	Treatment		
Dyskinesia		Development of oro- buccal dyskinesia low grade. Grade low- noticed by pation girlfriend release phenoma present.	a- ent &		
Medicine Details:					
RISPERIDONE (Suspected)		Reason:			
Batch:	Started:	Stopped:			
AMISULPRIDE (Suspected)		Reason:			
Batch:	Started:	Stonned:	0		
Batch: Abilify (Suspected)	Started:	Stopped: Reason: Othr&unspec me	0 stabolic diseases		
Batch: Abilify (Suspected) Tablet		Reason: Othr&unspec me			
Abilify (Suspected)		Reason: Othr&unspec me	tabolic diseases		
Abilify (Suspected) Tablet Batch: Laboratory Investigation	15.0 Started:	Reason: Othr&unspec me Milligram Daily C Stopped:	tabolic diseases Oral		
Abilify (Suspected) Tablet	15.0 Started:	Reason: Othr&unspec me Milligram Daily C Stopped:	tabolic diseases		

Report Run: 01/06/2007 01:54PM Database: pusime02 ADRS004 Page 210 of 220



Case Number: 225784

Reported: 13/02/2007

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 0.00

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Seq: 1

Hospitalisati	on:				Ag	e: 16Y		
Onset Da	ate:	DOB:						
Outcor	me: Unknown		Causality: Causality possible					
Reaction D								
Pre	eferred Term	Severity	Repo	ort Description		Treatmer		
Full blood co	unt decreased	Caused or prolonged inpatient hospitalisation	Blood count and decreased.	Neutrophils had	I	Aripiprazole ceased		
Neutrophil co	ount decreased	Caused or prolonged inpatient hospitalisation						
Medicine	ected)			son:				
Table Batcl		15.0 Started:	Milligram	Daily	Oral			
				Stoppe				
I aborator	v Investigati	ons:						
Date			ed Result		De	etails		
Additiona	Date Type Range Date Tested Result Details Additional Information:							
eport Run: 01/0	06/2007 01:54PM	Database: pusime02	A	ADRS004		Page 211	of 220	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

case Number. 220310	Seq. 1			
Reported: 05/03/2007			Weig	ht: 0.00
ospitalisation:				ge: 99u
Onset Date:			DC	OB:
Outcome: Not yet reco	overed		Causali	ity: Causality probable
eaction Details:				
Preferred Term	Severity	Report Des	scription	Treatment
Neuroleptic malignant syndroi	prolonged	Patient's symptoms inc talking, muscle rigidity, and elevated creatine k	muscle weakness	Abilify discontinued.
Blood creatine phosphokinase	e incr Caused or prolonged inpatient hospitalisation			
Speech disorder	Caused or prolonged inpatient hospitalisation			
Medicine Details:				
Abilify (Suspected)		Reason:		
Tablet	15.0	Milligram Daily	Oral	
Batch:	Started: 29/0	1/2007	Stopped: 05/02/2	2007
_aboratory Investigatio	ons:			
				petails

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

 Case Number:
 226616
 Seq: 1
 Gender: M

 Reported:
 14/03/2007
 Weight: 51.00

Hospitalisation: Age: 12

Onset Date: DOB: 02/02/1995

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Urinary incontinence, sleep excessive, vagueness.	
Confusional state			
Hypersomnia			

Medicine Details:

Medicine Details.					
DEXAMPHETAMINE SULPHATE (O	ther drug)	Reason:	Behavior disor	ders of childhoo	d
	10.0 Milligrar	n Daily			
Batch:	Started:		Stopped:	15/01/2007	
Aripiprazole (Suspected)		Reason:			
Tablet	10.0 Milligrar	n Daily		Oral	
Batch:	Started:		Stopped:	15/01/2007	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Taken off medication when custody given to father, urinary incontinence stopped within 1 week of stopping, remains dry 1 month later.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Case Number: 226805	Seq: 1		Ge	nder: M
Reported: 21/03/2007	-		We	ight: 0.00
spitalisation:				Age: 28Y
Onset Date:				DOB:
Outcome: Unknown			Caus	ality: Causality possible
action Details:				
Preferred Term	Severity		ort Description	Treatment
ve rolling		Patient's eyes we head" while rece	ere "rolling in back of iving aripiprazole.	
edicine Details:	450	Rea		
Tablet Batch:	15.0 Started:	Milligram	Daily Ora Stopped:	
aboratory Investigation Date Type	Range Date Test	ed Result		Details
Date Type	Range Date Testi	eu Resuit		Details
dditional Information:				
ort Run: 01/06/2007 01:54PM E	Database: pusime02	A	DRS004	Page 214 of 220



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Rep	ort	Detail	ls:
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Gender: F Case Number: 226806 Seq: 1

Weight: 0.00 Reported: 21/03/2007 **Hospitalisation:** Age: 21Y DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Onset Date:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Eye rolling		Patient experienced her eyes rolling back in her head while taking 30 mg of aripirazole daily.	

Medicine Details:

Medicine Details.					
Lexapro (Other drug)			Reason:		
Tablet				Oral	
Batch:	Started:			Stopped:	
Abilify (Suspected)			Reason:		
Tablet	30.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient is of Aboriginal descent had not experienced problems with her sight.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 226926 Seq: 1 Gender: F

Reported: 23/03/2007 Weight: 0.00 Hospitalisation: Age: 33

Onset Date: 05/12/2006 **DOB**: 03/07/1973

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	prolonged inpatient hospitalisation	Patient had symptoms of pins and needles which started on Fluoxamine and worsened when Aripiprazole was added on as a second treatment. Other symptoms were: word finding difficulty, dysarthriatic speech, weakness of the lower limbs with a tendency to falls.	Stopping Aripiprazole
Dysarthria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MEGICINE DELANS.					
Aripiprazole (Suspected)			Reason:	Unspecified so	chizophrenia
Tablet	10.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	19/12/2006
FLUVOXAMINE MALEATE (Suspected)			Reason:	Unspecified so	chizophrenia
Tablet	100.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Fluvoxamine is a cxb3A4 inhibitor (moderate) so may have increased Aripiprazole levels.

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Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Repor	t De	tails:
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Case Number: 226926 Seq: 1 Gender: F

Reported: 23/03/2007 Weight: 0.00 Hospitalisation: Age: 33

Onset Date: 05/12/2006 **DOB**: 03/07/1973

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphasia	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation		
Muscular weakness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Micalcinic Details.						
Aripiprazole (Suspected)			Reason:	Unspecified so	hizophrenia	
Tablet	10.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	19/12/2006	
FLUVOXAMINE MALEATE (Suspected)			Reason:	Unspecified so	hizophrenia	
Tablet	100.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		

Laboratory Investigations:

Additional Information:

Fluvoxamine is a cxb3A4 inhibitor (moderate) so may have increased Aripiprazole levels.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Laboratory Investigation Date Type		Date Tested	Result		Deta	ils	
		Date Tested	Result		Deta	ils	
		Date Toeted	Pacult	Г	Deta	ile	
Batch:	Sta	Started: Stoppe			pped:		
Tablet		30.0 Millig		ason: Daily Oral			
Medicine Details: Abilify (Suspected)			Do.				
Oculogyration		<u> </u> Oct	ulogyration				
Preferred Term	Sev	verity		ort Descriptio	n	Treatmen	t
eaction Details:					Causality:	Causality possi	ble
					DOB		
Onset Date: Outcome: Unknown							
Outcome: Unknown						0.00 99U	



Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 228346 Seq: 1 Gender: F
Reported: 09/05/2007 Weight: 0.00

Hospitalisation: Admitted to hospital Age: 46
Onset Date: 24/03/2007 DOB: 17/01/1961

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis	Life threatening	Patient developed rhabdomyolysis, fevers, rigor, suspected URTI and a fall before admission.	
Chills	Life threatening		
Neuroleptic malignant syndrome	Life threatening		
Pyrexia	Life threatening		

Medicine Details:

FLUVOXAMINE MALEATE (Other drug)			Reason:			
Tablet	100.0	Milligram			Oral	
Batch:	Started:			Stopped:		
QUETIAPINE (Other drug)			Reason:			
Tablet	400.0	Milligram			Oral	
Batch:	Started:			Stopped:		
CARBAMAZEPINE (Other drug)			Reason:			
Tablet	400.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		0
Aripiprazole (Suspected)			Reason:			
Tablet	15.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:	24/03/2007	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: Psychosis, depression, asthma and epilepsy.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Hospitalisation: Onset Date: Outcome: Reaction Detai	09/05/2007 Admitted to hospit 24/03/2007 Not yet recovered Is:				0.00	
Medicine Deta			B			
OLANZAPINE (Sus	spected)	7.5 Milligram	Reason: Daily			
Batch:		Started:	Daily	Stopped: 24/03/2007		
Laboratory In	vestigations:					
Additional Inf History: Psychosis	ormation: , depression, asthma	a and epilepsy.				

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