

## aripiprazole to end January 2009

				Case Group	Death Outcomes	Sole
Case Count				198	3	146
Medicine	Reaction Count	Blood and lymphatic system disorders	Pancytopenia	1	0	1
			Leukocytosis	1	0	0
			Neutropenia	2	0	2
			Blood and lymphatic system disorders	4	0	3
		Cardiac disorders	Conduction disorder	1	0	1
			Wolff-Parkinson-White syndrome	1	0	1
			Arrhythmia	1	0	1
			Bradycardia	1	0	1
			Tachycardia	9	0	2
			Sinus tachycardia	1	0	1
			Supraventricular tachycardia	1	0	0
			Cardiac arrest	1	0	0
			Cyanosis	1	0	1
			Palpitations	2	0	1
			Dilatation ventricular	1	0	0
			Ventricular dysfunction	1	0	0
			Cardiac disorders	21	0	9
			Congenital, familial and genetic disorders	Heart disease congenital	1	0
		Congenital cardiovascular anomaly		1	0	1
		Trisomy 21		1	0	0
		Limb malformation		1	0	0
		Kidney malformation		1	0	0
		Congenital, familial and genetic disorders		5	0	1
		Endocrine disorders	Hyperprolactinaemia	1	0	0
			Inappropriate antidiuretic hormone secretion	1	0	1
			Endocrine disorders	2	0	1
		Eye disorders	Eye disorder	1	0	1
			Oculogyric crisis	3	0	3
			Mydriasis	1	0	0
			Eye rolling	2	0	2
			Photopsia	1	0	1
			Vision blurred	5	0	4
			Eye disorders	13	0	11
Gastrointestinal disorders	Dental caries	3	0	3		
	Pancreatitis	2	0	2		
	Diarrhoea	3	0	2		
	Constipation	1	0	0		
	Dyspepsia	4	0	4		
	Abdominal pain	2	0	2		
	Abdominal pain upper	1	0	1		

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Gastrointestinal disorders	Abdominal discomfort	1	0	1
			Dysphagia	1	0	1
			Faecal incontinence	2	0	2
			Nausea	11	0	10
			Vomiting	12	0	12
			Lip swelling	1	0	1
			Hypoaesthesia oral	1	0	1
			Salivary hypersecretion	2	0	2
			Swollen tongue	2	0	1
			Tongue oedema	2	0	1
			<b>Gastrointestinal disorders</b>	<b>51</b>	<b>0</b>	<b>46</b>
		General disorders and administration site conditions	Pyrexia	7	0	2
			Death	2	1	1
			Sudden death	1	1	0
			Asthenia	1	0	0
			Fatigue	3	0	2
			Malaise	3	0	3
			Gait disturbance	6	0	4
			Condition aggravated	2	0	2
			Exercise tolerance decreased	1	0	1
			Irritability	1	0	1
			Oedema peripheral	1	0	1
			Chest pain	1	0	1
			Chills	2	0	0
			Feeling abnormal	1	0	1
			Feeling cold	1	0	1
			Feeling hot	1	0	1
			Feeling of body temperature change	1	0	1
			Thirst decreased	1	0	1
			Drug interaction	3	0	0
			Drug ineffective	6	0	4
			Rebound effect	1	0	0
			<b>General disorders and administration site conditions</b>	<b>46</b>	<b>2</b>	<b>27</b>
			Hepatobiliary disorders	Hepatic function abnormal	1	0
		Hepatorenal failure		1	0	1
		<b>Hepatobiliary disorders</b>		<b>2</b>	<b>0</b>	<b>2</b>
		Immune system disorders	Hypersensitivity	1	0	1
			<b>Immune system disorders</b>	<b>1</b>	<b>0</b>	<b>1</b>
		Infections and infestations	Cellulitis	1	0	0
			Nasopharyngitis	1	0	0
			Upper respiratory tract infection	1	0	1
			<b>Infections and infestations</b>	<b>3</b>	<b>0</b>	<b>1</b>

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Injury, poisoning and procedural complications	Drug exposure during pregnancy	2	0	1
			Excoriation	1	0	1
			Fall	1	0	0
			Drug dispensing error	1	0	1
			Drug prescribing error	1	0	0
			Accidental overdose	1	0	1
			Overdose	4	0	4
			Injury, poisoning and procedural complications	11	0	8
		Investigations	Echocardiogram abnormal	1	0	0
			Ejection fraction decreased	1	0	0
			Electrocardiogram T wave abnormal	1	0	1
			Blood pressure increased	3	0	2
			Blood creatine phosphokinase increased	19	1	9
			Blood amylase increased	1	0	0
			Full blood count decreased	1	0	1
			Neutrophil count decreased	2	0	1
			White blood cell count decreased	1	0	0
			Alanine aminotransferase increased	1	0	1
			Liver function test abnormal	3	0	2
			Blood cholesterol increased	1	0	1
			Low density lipoprotein increased	1	0	1
			Oxygen saturation decreased	1	0	0
			Blood glucose increased	1	0	0
			Corneal reflex decreased	1	0	1
			Body temperature increased	3	0	2
			Weight decreased	1	0	1
			Weight increased	2	0	1
			Blood creatine decreased	1	0	1
			Blood urea decreased	1	0	1
			Urine output increased	1	0	1
			Antipsychotic drug level increased	1	1	0
			Drug level increased	1	0	0
		Blood chloride decreased	1	0	1	
		Investigations	51	2	28	
		Metabolism and nutrition disorders	Tetany	1	0	1
			Diabetic ketoacidosis	2	0	2
			Polydipsia	1	0	0
Hypokalaemia	1		0	0		
Hyponatraemia	1		0	1		
Dehydration	1		0	0		
Diabetes mellitus	1		0	1		

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole		
		Metabolism and nutrition disorders	Hyperglycaemia	1	0	1	
			Metabolism and nutrition disorders	9	0	6	
		Musculoskeletal and connective tissue disorders	Arthralgia	2	0	2	
			Joint stiffness	1	0	1	
			Myositis	1	0	1	
			Myalgia	3	0	1	
			Muscle spasms	5	0	5	
			Muscle tightness	2	0	0	
			Muscle twitching	3	0	2	
			Muscle rigidity	5	0	4	
			Nuchal rigidity	2	0	1	
			Torticollis	1	0	0	
			Muscular weakness	2	0	2	
			Rhabdomyolysis	1	0	0	
			Musculoskeletal stiffness	2	0	1	
			Back pain	2	0	2	
			Neck pain	2	0	2	
			Musculoskeletal and connective tissue disorders	34	0	24	
			Nervous system disorders	Facial palsy	1	0	1
				Facial paresis	1	0	1
				Headache	5	0	5
		Amnesia		2	0	1	
		Cognitive disorder		1	0	0	
		Disturbance in attention		1	0	1	
		Chorea		1	0	1	
		Akathisia		12	0	10	
		Bradykinesia		1	0	1	
		Dyskinesia		9	0	7	
		Extrapyramidal disorder		7	0	5	
		Psychomotor hyperactivity		1	0	1	
		Tardive dyskinesia		4	0	4	
		Dystonia		9	0	5	
		Opisthotonus		1	0	1	
		Diplegia		1	0	1	
		Locked-in syndrome		1	0	0	
		Cogwheel rigidity		1	0	0	
		Parkinsonism		3	0	2	
		Tremor		8	0	6	
		Hyperreflexia	3	0	2		
		Coordination abnormal	2	0	1		
		Nystagmus	1	0	1		
		Consciousness fluctuating	1	0	0		

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Nervous system disorders	Depressed level of consciousness	1	0	0
			Loss of consciousness	1	0	0
			Sedation	1	0	1
			Somnolence	8	0	7
			Syncope	1	0	1
			Psychomotor skills impaired	1	0	0
			Clonus	1	0	1
			Dizziness	9	0	8
			Drooling	2	0	2
			Myoclonus	2	0	2
			Paraesthesia	1	0	0
			Dysphasia	1	0	1
			Incoherent	1	0	1
			Speech disorder	2	0	2
			Adrenergic syndrome	1	0	0
			Hypertonia	3	0	3
			Neuroleptic malignant syndrome	18	1	8
			Serotonin syndrome	1	0	1
			Neuropathy peripheral	1	0	1
			Grand mal convulsion	1	0	1
			Convulsion	4	0	4
			Convulsive threshold lowered	1	0	1
			Hypersomnia	1	0	1
		<b>Nervous system disorders</b>	<b>140</b>	<b>1</b>	<b>103</b>	
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	0
			Pregnancy, puerperium and perinatal conditions	1	0	0
		Psychiatric disorders	Agitation	12	1	10
			Anxiety	6	0	4
			Nervousness	1	0	0
			Fear	1	0	1
			Obsessive thoughts	1	1	1
			Obsessive-compulsive disorder	1	0	1
			Restlessness	6	0	6
			Expressive language disorder	1	0	0
			Confusional state	5	0	3
			Disorientation	2	0	2
			Delirium	4	0	0
			Depression	2	0	1
			Feeling of despair	1	0	0
			Psychomotor retardation	1	0	0
			Delusion	1	0	1
		Persecutory delusion	1	0	1	

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Psychiatric disorders</b>	Hallucination	3	0	3
			Hallucination, auditory	4	0	1
			Thinking abnormal	2	0	2
			Hypomania	1	0	1
			Mania	7	1	7
			Emotional distress	1	0	1
			Euphoric mood	1	0	1
			Mood swings	1	0	1
			Aggression	3	0	3
			Paranoia	5	0	5
			Abnormal behaviour	1	0	1
			Mental status changes	1	0	0
			Intentional drug misuse	1	0	1
			Withdrawal syndrome	3	0	2
			Psychotic disorder	7	0	4
			Schizophrenia	1	0	1
			Disturbance in sexual arousal	1	0	1
			Insomnia	7	0	5
			Abnormal sleep-related event	1	0	1
			Somnambulism	1	0	1
			Sleep disorder	3	0	3
			Intentional self-injury	2	0	2
			Suicidal ideation	2	1	1
		<b>Psychiatric disorders</b>	<b>105</b>	<b>4</b>	<b>79</b>	
		<b>Renal and urinary disorders</b>	Renal failure acute	1	0	0
			Dysuria	2	0	1
			Pollakiuria	1	0	1
			Urinary incontinence	3	0	2
			Urinary retention	2	0	0
			<b>Renal and urinary disorders</b>	<b>9</b>	<b>0</b>	<b>4</b>
		<b>Reproductive system and breast disorders</b>	Galactorrhoea	1	0	1
			Amenorrhoea	1	0	1
			Menorrhagia	1	0	0
			Ejaculation failure	2	0	0
			Erectile dysfunction	3	0	3
			Priapism	1	0	1
			<b>Reproductive system and breast disorders</b>	<b>9</b>	<b>0</b>	<b>6</b>
		<b>Respiratory, thoracic and mediastinal disorders</b>	Pulmonary embolism	1	1	0
			Dyspnoea	3	0	2
			Hiccups	2	0	2
			Rhinorrhoea	1	0	1
			Laryngospasm	1	0	0

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		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>Respiratory, thoracic and mediastinal disorders</b>	8	1	5
		<b>Skin and subcutaneous tissue disorders</b>	<b>Blister</b>	1	0	1
			<b>Erythema</b>	1	0	1
			<b>Rash papular</b>	1	0	1
			<b>Pruritus</b>	3	0	3
			<b>Rash pruritic</b>	1	0	1
			<b>Psoriasis</b>	1	0	1
			<b>Rash</b>	3	0	3
			<b>Hyperhidrosis</b>	7	0	3
			<b>Night sweats</b>	1	0	0
			<b>Skin and subcutaneous tissue disorders</b>	19	0	14
		<b>Social circumstances</b>	<b>Promiscuity</b>	2	0	2
			<b>Bedridden</b>	1	0	1
			<b>Treatment noncompliance</b>	1	0	1
			<b>Social circumstances</b>	4	0	4
		<b>Surgical and medical procedures</b>	<b>Therapy regimen changed</b>	7	0	5
			<b>Surgical and medical procedures</b>	7	0	5
		<b>Vascular disorders</b>	<b>Circulatory collapse</b>	1	0	1
			<b>Hypotension</b>	4	0	1
			<b>Orthostatic hypotension</b>	2	0	2
			<b>Deep vein thrombosis</b>	1	0	1
			<b>Pallor</b>	1	0	0
			<b>Hypertension</b>	3	0	3
			<b>Vascular disorders</b>	12	0	8
		<b>Reaction</b>	567	10	396	