

Cube updated:15/12/2009 7:30:39 AM

## **Medicine summary (Antidepressants 10-19 year olds to January 2009)**

			Case Group	Death Outcomes	Sole
Case Count			<b>513</b>	<b>5</b>	<b>388</b>
Reaction Count	Blood and lymphatic system disorders	Anaemia	4	0	2
		Aplastic anaemia	1	0	1
		Platelet disorder	2	0	2
		Thrombocytopenia	2	0	2
		Leukopenia	1	0	1
		Agranulocytosis	1	0	1
		Neutropenia	5	0	3
		<b>Blood and lymphatic system disorders</b>	<b>16</b>	<b>0</b>	<b>12</b>
	Cardiac disorders	Atrioventricular block first degree	1	0	0
		Bundle branch block bilateral	1	0	0
		Arrhythmia	1	0	1
		Extrasystoles	1	0	1
		Tachycardia	8	0	5
		Supraventricular tachycardia	1	0	0
		Cardiac arrest	1	0	0
		Electromechanical dissociation	1	0	0
		Ventricular tachycardia	1	1	1
		Palpitations	4	0	4
		Myocardial infarction	1	0	0
		<b>Cardiac disorders</b>	<b>21</b>	<b>1</b>	<b>12</b>
	Congenital, familial and genetic disorders	Heart disease congenital	1	0	1
		Coarctation of the aorta	1	0	1
		Tourette's disorder	2	0	2
		<b>Congenital, familial and genetic disorders</b>	<b>4</b>	<b>0</b>	<b>4</b>
	Ear and labyrinth disorders	Deafness	4	0	4
		Vertigo	3	0	3
		<b>Ear and labyrinth disorders</b>	<b>7</b>	<b>0</b>	<b>7</b>
	Endocrine disorders	Hyperprolactinaemia	1	0	1
		Inappropriate antidiuretic hormone secretion	1	0	1
		<b>Endocrine disorders</b>	<b>2</b>	<b>0</b>	<b>2</b>
	Eye disorders	Eye disorder	1	0	1
		Eye pain	1	0	1
		Eye swelling	1	0	1
		Ocular hyperaemia	1	0	0
		Oculogyric crisis	3	0	2
		Mydriasis	13	0	9
		Pupil fixed	1	0	1
		Pupillary reflex impaired	1	0	0
		Eye rolling	1	0	0
		Photophobia	3	0	2
		Night blindness	1	0	1

Cube updated:15/12/2009 7:30:39 AM

## **Medicine summary (Antidepressants 10-19 year olds to January 2009)**

Reaction Count			Case Group	Death Outcomes	Sole
Reaction Count	Eye disorders	Sudden visual loss	1	0	1
		Accommodation disorder	1	0	1
		Diplopia	1	0	1
		Visual impairment	10	0	8
		<b>Eye disorders</b>	<b>40</b>	<b>0</b>	<b>29</b>
Reaction Count	Gastrointestinal disorders	Gingival bleeding	1	0	1
		Pancreatitis	1	0	1
		Haematemesis	2	0	2
		Oesophagitis	1	0	1
		Diarrhoea	6	0	1
		Dyspepsia	2	0	1
		Flatulence	1	0	0
		Abdominal pain	7	1	7
		Abdominal pain upper	1	0	1
		Dysphagia	3	0	2
		Faecal incontinence	1	0	1
		Nausea	52	0	46
		Vomiting	15	1	15
		Ileus	1	0	0
		Lip swelling	1	0	1
		Mouth ulceration	1	0	1
		Dry mouth	4	0	4
		Salivary hypersecretion	3	0	3
		Glossitis	1	0	1
		Tongue ulceration	1	0	1
		Swollen tongue	1	0	0
		<b>Gastrointestinal disorders</b>	<b>106</b>	<b>2</b>	<b>90</b>
Reaction Count	General disorders and administration site conditions	Hyperthermia malignant	1	0	1
		Pyrexia	8	0	5
		Sudden death	1	1	1
		Asthenia	5	0	4
		Fatigue	9	0	7
		Malaise	7	0	4
		Gait disturbance	2	0	2
		Condition aggravated	1	0	1
		Influenza like illness	3	0	2
		Irritability	1	0	1
		Face oedema	7	0	3
		Gravitational oedema	1	0	1
		Oedema	1	0	1
		Oedema peripheral	2	0	0
		Chest pain	8	0	5

Cube updated:15/12/2009 7:30:39 AM

## **Medicine summary (Antidepressants 10-19 year olds to January 2009)**

Reaction Count			Case Group	Death Outcomes	Sole
	General disorders and administration site conditions	Pain	2	0	1
		Chest discomfort	1	0	1
		Chills	3	0	1
		Drug interaction	2	0	0
		Drug ineffective	14	1	6
		Therapeutic response decreased	1	0	0
		Drug withdrawal syndrome	2	0	1
		<b>General disorders and administration site conditions</b>	<b>82</b>	<b>2</b>	<b>48</b>
	Hepatobiliary disorders	Hepatitis cholestatic	1	0	1
		Jaundice	1	0	0
		Hepatic function abnormal	10	0	8
		Hepatic failure	1	0	0
		Hepatitis	1	0	0
		<b>Hepatobiliary disorders</b>	<b>14</b>	<b>0</b>	<b>9</b>
	Immune system disorders	Anaphylactoid reaction	3	0	3
		<b>Immune system disorders</b>	<b>3</b>	<b>0</b>	<b>3</b>
	Infections and infestations	Pyomyositis	1	0	1
		Meningitis	2	0	2
		Otitis media	1	0	0
		Pharyngitis	1	0	0
		Herpes simplex	1	0	1
		Viral infection	1	0	0
		<b>Infections and infestations</b>	<b>7</b>	<b>0</b>	<b>4</b>
	Injury, poisoning and procedural complications	Drug exposure during pregnancy	1	0	0
		Contusion	1	0	0
		Medication error	1	0	1
		Intentional overdose	5	0	2
		Multiple drug overdose intentional	1	0	0
		Overdose	2	0	1
		<b>Injury, poisoning and procedural complications</b>	<b>11</b>	<b>0</b>	<b>4</b>
	Investigations	Echocardiogram abnormal	1	0	0
		Ejection fraction decreased	1	0	0
		Electrocardiogram QT prolonged	2	0	0
		Heart rate increased	1	0	1
		Thyroid function test abnormal	1	0	1
		Blood creatine phosphokinase increased	3	0	1
		Bleeding time prolonged	2	0	1
		Prothrombin time prolonged	1	0	0
		Alanine aminotransferase increased	1	0	0
		Aspartate aminotransferase increased	1	0	0
		Lipids abnormal	1	0	0

**Medicine summary (Antidepressants 10-19 year olds to January 2009)**

Reaction Count			Case Group	Death Outcomes	Sole
	Investigations	Weight decreased	6	1	4
		Weight increased	10	0	6
		Blood creatinine increased	1	0	0
		Drug level increased	1	0	0
		<b>Investigations</b>	<b>33</b>	<b>1</b>	<b>14</b>
	Metabolism and nutrition disorders	Decreased appetite	7	0	5
		Increased appetite	2	0	2
		Tetany	1	0	1
		Polydipsia	1	0	1
		Hypokalaemia	3	0	1
		Hyponatraemia	4	0	3
		Dehydration	3	0	3
		Hypovolaemia	1	0	0
		Diabetes mellitus	2	0	1
		Hyperglycaemia	1	0	1
		Hypoglycaemia	2	0	1
		<b>Metabolism and nutrition disorders</b>	<b>27</b>	<b>0</b>	<b>19</b>
	Musculoskeletal and connective tissue disorders	Arthralgia	4	0	3
		Myalgia	9	0	6
		Muscle spasms	6	0	4
		Muscle tightness	2	0	2
		Muscle twitching	15	0	11
		Trismus	1	0	1
		Myopathy	1	0	1
		Rhabdomyolysis	2	0	1
		Back pain	1	0	1
		<b>Musculoskeletal and connective tissue disorders</b>	<b>41</b>	<b>0</b>	<b>30</b>
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	1	0	1
		<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>1</b>	<b>0</b>	<b>1</b>
	Nervous system disorders	Encephalopathy	1	0	1
		Headache	37	1	27
		Amnesia	7	0	5
		Cognitive disorder	1	0	1
		Disturbance in attention	3	0	2
		Mental impairment	1	0	1
		Choreoathetosis	6	0	5
		Akathisia	7	1	5
		Dyskinesia	7	0	6
		Extrapyramidal disorder	3	0	1
		Hyperkinesia	5	0	3

Cube updated:15/12/2009 7:30:39 AM

## **Medicine summary (Antidepressants 10-19 year olds to January 2009)**

Reaction Count			Case Group	Death Outcomes	Sole
	Nervous system disorders	Movement disorder	1	0	1
		Dystonia	21	0	13
		Opisthotonus	1	0	0
		Hemiparesis	1	0	0
		Paralysis	1	0	1
		Tremor	17	0	14
		Hyperreflexia	2	0	2
		Ataxia	6	0	4
		Coordination abnormal	3	0	3
		Nystagmus	2	0	2
		Coma	1	0	0
		Aphasia	1	0	1
		Loss of consciousness	5	0	5
		Sedation	2	0	0
		Somnolence	17	0	13
		Stupor	1	0	1
		Syncope	10	0	9
		Central nervous system lesion	1	0	0
		Clonus	1	0	1
		Dizziness	32	0	25
		Neurological symptom	1	0	0
		Crying	1	0	1
		Hyperaesthesia	1	0	0
		Paraesthesia	6	0	3
		Hypoesthesia	3	0	2
		Sensory disturbance	1	0	0
		Dysarthria	3	0	2
		Speech disorder	4	0	3
		Visual field defect	1	0	1
		Adrenergic syndrome	1	0	0
		Anticholinergic syndrome	1	0	0
		Hypertonia	9	0	5
		Neuroleptic malignant syndrome	1	0	0
		Serotonin syndrome	8	0	3
		Grand mal convulsion	9	0	6
		Convulsion	31	0	23
		Epilepsy	1	0	1
		Poor quality sleep	3	1	3
		<b>Nervous system disorders</b>	<b>289</b>	<b>3</b>	<b>205</b>
	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	1
		Premature labour	2	0	1
		Pre-eclampsia	1	0	0

## **Medicine summary (Antidepressants 10-19 year olds to January 2009)**

Reaction Count		Case Group	Death Outcomes	Sole
	Pregnancy, puerperium and perinatal conditions	<b>Pregnancy, puerperium and perinatal conditions</b>	<b>4</b>	<b>0</b>
	Psychiatric disorders	Agitation	32	0
		Anxiety	12	0
		Nervousness	2	0
		Panic attack	2	0
		Neurosis	1	0
		Restlessness	2	0
		Bruxism	2	0
		Tic	2	0
		Learning disorder	1	0
		Confusional state	18	0
		Disorientation	1	0
		Delirium	4	0
		Depression	9	0
		Depressed mood	1	0
		Depersonalisation	3	0
		Dissociation	2	0
		Delusion	1	0
		Hallucination	19	0
		Hallucination, visual	1	0
		Thinking abnormal	4	0
		Eating disorder	2	0
		Bipolar disorder	1	0
		Mania	14	0
		Affect lability	1	0
		Anger	4	0
		Euphoric mood	6	0
		Mood swings	4	0
		Apathy	1	0
		Aggression	26	0
		Homicidal ideation	3	0
		Paranoia	4	0
		Personality change	1	0
		Personality disorder	2	0
		Abnormal behaviour	2	0
		Withdrawal syndrome	16	0
		Psychotic disorder	6	0
		Anorgasmia	1	0
		Insomnia	17	0
		Abnormal dreams	2	0
		Nightmare	4	1

**Medicine summary (Antidepressants 10-19 year olds to January 2009)**

Reaction Count			Case Group	Death Outcomes	Sole
Psychiatric disorders	Psychiatric disorders	Somnambulism	3	0	3
		Sleep disorder	4	0	3
		Completed suicide	2	2	2
		Intentional self-injury	4	0	3
		Self injurious behaviour	6	0	2
		Self-injurious ideation	1	0	1
		Suicidal behaviour	3	0	2
		Suicidal ideation	17	0	11
		Suicide attempt	27	1	16
		<b>Psychiatric disorders</b>	<b>303</b>	<b>4</b>	<b>215</b>
Renal and urinary disorders	Renal and urinary disorders	Tubulointerstitial nephritis	1	0	1
		Anuria	1	0	0
		Renal failure acute	1	0	1
		Dysuria	1	0	1
		Micturition disorder	2	0	1
		Pollakiuria	2	0	2
		Urinary hesitation	1	0	1
		Urinary incontinence	6	0	3
		Urinary retention	2	0	2
		Polyuria	3	0	3
		Calculus bladder	1	0	0
Reproductive system and breast disorders	Reproductive system and breast disorders	<b>Renal and urinary disorders</b>	<b>21</b>	<b>0</b>	<b>15</b>
		Breast enlargement	1	0	1
		Gynaecomastia	3	0	3
		Breast pain	1	0	1
		Galactorrhoea	6	0	5
		Menstrual disorder	2	0	2
		Metrorrhagia	1	0	1
		Menorrhagia	2	0	1
		Perineal pain	1	0	1
		Erectile dysfunction	2	0	1
Respiratory, thoracic and mediastinal disorders	Respiratory, thoracic and mediastinal disorders	<b>Reproductive system and breast disorders</b>	<b>19</b>	<b>0</b>	<b>16</b>
		Wheezing	1	0	1
		Pulmonary embolism	1	0	0
		Dyspnoea	6	0	3
		Hyperventilation	2	0	1
		Respiratory arrest	1	0	1
		Haemoptysis	1	0	1
		Hiccups	1	0	1
		Respiratory disorder	1	0	1
		Yawning	2	0	2
		Epistaxis	8	0	7

Cube updated:15/12/2009 7:30:39 AM

## **Medicine summary (Antidepressants 10-19 year olds to January 2009)**

Reaction Count			Case Group	Death Outcomes	Sole
	Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	1	0	1
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>25</b>	<b>0</b>	<b>19</b>
	Skin and subcutaneous tissue disorders	Angioedema	5	0	2
		Periorbital oedema	1	0	0
		Urticaria	15	0	13
		Stevens-Johnson syndrome	1	0	0
		Swelling face	1	0	1
		Eczema	1	0	1
		Rash erythematous	1	0	0
		Dermatitis exfoliative	1	0	1
		Skin exfoliation	1	0	1
		Photosensitivity reaction	4	0	4
		Pruritus	7	0	5
		Rash	16	1	15
		Rash macular	1	0	0
		Rash maculo-papular	4	0	3
		Rash vesicular	2	0	2
		Erythema nodosum	2	0	2
		Acne	7	0	5
		Alopecia	7	0	4
		Hyperhidrosis	12	0	8
		Hypohidrosis	1	0	1
		Henoch-Schonlein purpura	1	0	1
		Purpura	9	0	9
		<b>Skin and subcutaneous tissue disorders</b>	<b>100</b>	<b>1</b>	<b>78</b>
	Social circumstances	Physical assault	1	0	1
		<b>Social circumstances</b>	<b>1</b>	<b>0</b>	<b>1</b>
	Surgical and medical procedures	Drug therapy changed	2	0	2
		Therapy regimen changed	1	0	0
		<b>Surgical and medical procedures</b>	<b>3</b>	<b>0</b>	<b>2</b>
	Vascular disorders	Peripheral ischaemia	2	0	1
		Shock	1	0	0
		Hypotension	4	0	2
		Orthostatic hypotension	4	0	3
		Deep vein thrombosis	2	1	1
		Flushing	2	0	1
		Pallor	2	0	2
		Haemorrhage	2	0	0
		Hypertension	2	0	0
		<b>Vascular disorders</b>	<b>21</b>	<b>1</b>	<b>10</b>
	<b>Reaction</b>		<b>1201</b>	<b>15</b>	<b>851</b>