

**Medicine summary - citalopram (to end January 2009)**

			Case Group	Death Outcomes	Sole
Case Count			734	13	493
Reaction Count	Blood and lymphatic system disorders	Iron deficiency anaemia	1	0	1
		Anaemia	1	0	1
		Pancytopenia	2	0	0
		Thrombocytopenia	3	0	2
		Lymphadenopathy	1	0	1
		Eosinophilia	2	0	1
		Leukocytosis	1	0	0
		Leukopenia	3	0	1
		Neutropenia	4	0	1
		<b>Blood and lymphatic system disorders</b>	<b>18</b>	<b>0</b>	<b>8</b>
	Cardiac disorders	Atrioventricular block	1	0	0
		Arrhythmia	1	0	0
		Bradycardia	4	0	4
		Extrasystoles	1	0	1
		Tachycardia	16	0	9
		Arrhythmia supraventricular	1	0	1
		Sick sinus syndrome	1	0	1
		Sinus bradycardia	1	0	1
		Supraventricular tachycardia	1	0	0
		Cardiac arrest	3	2	1
		Torsade de pointes	3	1	1
		Ventricular tachycardia	1	0	0
		Cyanosis	1	1	0
		Palpitations	23	0	18
		Myocardial infarction	1	0	0
Myocardial ischaemia		1	1	1	
Cardiomyopathy		1	1	0	
<b>Cardiac disorders</b>	<b>61</b>	<b>6</b>	<b>38</b>		
Congenital, familial and genetic disorders	Ventricular hypoplasia	1	1	1	
	Ventricular septal defect	1	0	0	
	Fallot's tetralogy	1	0	0	
	Congenital anomaly	1	1	1	
	<b>Congenital, familial and genetic disorders</b>	<b>4</b>	<b>2</b>	<b>2</b>	
Ear and labyrinth disorders	Ear pain	1	0	1	
	Deafness unilateral	1	0	1	
	Hearing impaired	1	0	1	
	Hyperacusis	1	0	1	
	Tinnitus	5	0	5	
	Vertigo	1	0	1	
	<b>Ear and labyrinth disorders</b>	<b>10</b>	<b>0</b>	<b>10</b>	
Endocrine disorders	Hyperprolactinaemia	2	0	1	

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			Case Group	Death Outcomes	Sole	
Reaction Count	Endocrine disorders	Inappropriate antidiuretic hormone secretion	13	0	11	
		<b>Endocrine disorders</b>	<b>15</b>	<b>0</b>	<b>12</b>	
	Eye disorders	Eye pain	2	0	1	
		Eye swelling	2	0	2	
		Glaucoma	3	0	2	
		Conjunctival haemorrhage	1	0	1	
		Keratitis	1	0	1	
		Blepharospasm	1	0	1	
		Strabismus	1	0	1	
		Mydriasis	6	0	4	
		Photophobia	1	0	1	
		Accommodation disorder	2	0	1	
		Diplopia	3	0	2	
		Photopsia	1	0	1	
		Vision blurred	7	0	6	
		Visual impairment	16	0	14	
		<b>Eye disorders</b>	<b>47</b>	<b>0</b>	<b>38</b>	
		Gastrointestinal disorders	Abdominal hernia	1	0	1
			Anorectal disorder	1	0	1
	Tooth disorder		1	0	0	
	Toothache		1	0	1	
	Tooth discolouration		1	0	0	
	Gingivitis		1	0	1	
	Gingival bleeding		1	0	1	
	Pancreatitis		1	0	0	
	Rectal haemorrhage		1	0	0	
	Gastrointestinal haemorrhage		2	1	0	
	Haematemesis		3	0	2	
	Melaena		2	1	0	
Colitis	1		0	0		
Gastritis	3		1	1		
Crohn's disease	1		0	1		
Diarrhoea	36		0	25		
Constipation	3		0	2		
Gastrointestinal motility disorder	1		0	1		
Ileus paralytic	2		0	0		
Dyspepsia	6		0	6		
Eructation	1	0	1			
Abdominal distension	3	0	3			
Flatulence	7	0	6			
Abdominal pain	14	0	9			
Abdominal pain upper	4	0	3			

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			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Abdominal discomfort	1	0	1
		Breath odour	2	0	1
		Dysphagia	3	0	2
		Nausea	96	0	69
		Vomiting	33	0	22
		Intestinal obstruction	2	0	0
		Duodenal ulcer	1	0	0
		Lip oedema	1	0	1
		Lip swelling	4	0	2
		Hypoaesthesia oral	1	0	1
		Oral discomfort	1	0	1
		Mouth ulceration	2	0	2
		Dry mouth	15	0	12
		Salivary hypersecretion	1	0	0
		Glossitis	1	0	1
		Swollen tongue	2	0	1
		<b>Gastrointestinal disorders</b>	<b>264</b>	<b>3</b>	<b>181</b>
	General disorders and administration site conditions	Hypothermia	1	0	1
		Pyrexia	13	0	7
		Death	1	1	0
		Sudden death	3	3	0
		Asthenia	6	0	5
		Fatigue	26	0	18
		Malaise	12	0	9
		Gait disturbance	6	0	2
		Condition aggravated	1	0	0
		Influenza like illness	2	0	2
		Irritability	4	0	3
		Swelling	1	0	1
		Face oedema	4	0	4
		Generalised oedema	3	0	2
		Oedema	3	0	1
		Oedema peripheral	3	0	3
Chest pain		12	0	9	
Pain		4	0	4	
Chest discomfort		3	0	2	
Chills		2	0	1	
Feeling abnormal	2	0	1		
Feeling cold	1	0	0		
Feeling hot	2	0	0		
Feeling jittery	2	0	1		
Thirst	3	0	2		

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			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site conditions	Drug interaction	3	0	0
		Drug ineffective	14	0	13
		Drug tolerance increased	1	1	0
		Therapeutic response decreased	1	0	1
		Therapeutic response unexpected	1	0	1
		Drug withdrawal syndrome	2	0	2
		Drug withdrawal syndrome neonatal	3	0	3
		<b>General disorders and administration site conditions</b>	<b>145</b>	<b>5</b>	<b>98</b>
	Hepatobiliary disorders	Vanishing bile duct syndrome	2	0	2
		Hepatitis cholestatic	4	0	3
		Jaundice	2	0	1
		Jaundice cholestatic	1	0	1
		Liver disorder	1	0	1
		Hepatic function abnormal	1	0	1
		Hepatic failure	1	0	1
		Hepatomegaly	1	0	0
		Hepatitis	3	0	0
		<b>Hepatobiliary disorders</b>	<b>16</b>	<b>0</b>	<b>10</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	Vaginal infection	1	0	1
		Infection	1	0	1
		Bronchitis	1	0	1
		Pneumonia	2	0	1
		Rash pustular	1	0	1
		Pharyngitis	2	0	2
		Rhinitis	3	0	3
		Sinusitis	1	0	1
		Upper respiratory tract infection	2	0	2
		Herpes simplex	1	0	1
		Influenza	1	0	1
		<b>Infections and infestations</b>	<b>16</b>	<b>0</b>	<b>15</b>
	Injury, poisoning and procedural complications	Drug exposure during pregnancy	4	2	2
Fall		3	0	1	
Contusion		3	0	2	
Intentional overdose		2	0	2	
Overdose		4	0	2	
<b>Injury, poisoning and procedural complications</b>		<b>16</b>	<b>2</b>	<b>9</b>	
Investigations	Electrocardiogram QT prolonged	4	0	1	
	Electrocardiogram T wave inversion	1	0	0	

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			Case Group	Death Outcomes	Sole		
Reaction Count	Investigations	Electrocardiogram abnormal	1	0	0		
		Blood pressure increased	2	0	1		
		Blood creatine phosphokinase increased	6	0	1		
		Prothrombin time prolonged	1	0	0		
		Gamma-glutamyltransferase increased	1	0	1		
		Liver function test abnormal	5	0	1		
		Oxygen saturation decreased	1	0	1		
		Blood glucose decreased	1	0	0		
		Blood glucose increased	1	0	1		
		Electroencephalogram abnormal	1	0	0		
		Apgar score low	1	0	1		
		Respiratory rate increased	1	0	0		
		Weight decreased	11	0	9		
		Weight increased	5	0	4		
		C-reactive protein increased	1	0	1		
		Blood creatinine increased	1	0	1		
		Drug level decreased	1	0	0		
		Drug level increased	4	2	0		
			<b>Investigations</b>		<b>50</b>	<b>2</b>	<b>23</b>
			Metabolism and nutrition disorders	Decreased appetite	11	0	8
		Tetany		2	0	0	
		Hypomagnesaemia		1	0	0	
		Electrolyte imbalance		1	0	0	
		Polydipsia		1	0	1	
		Hyperkalaemia		3	0	2	
		Hypokalaemia		3	0	1	
		Hypernatraemia		2	0	2	
		Hyponatraemia		64	0	33	
		Dehydration		2	0	1	
		Alcohol intolerance		1	0	0	
		Diabetes mellitus		1	0	0	
		Hyperinsulinaemia		2	0	2	
		Hypoglycaemia		1	0	1	
		Hypoglycaemia neonatal		1	0	1	
		<b>Metabolism and nutrition disorders</b>			<b>96</b>	<b>0</b>	<b>52</b>
		Musculoskeletal and connective tissue disorders	Exostosis	1	0	1	
			Bone pain	1	0	1	
			Sjogren's syndrome	1	0	1	
			Arthralgia	4	0	4	
			Joint stiffness	1	0	1	
			Myalgia	13	0	11	
			Muscle spasms	4	0	4	

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			Case Group	Death Outcomes	Sole
Reaction Count	Musculoskeletal and connective tissue disorders	Muscle twitching	6	0	4
		Muscle rigidity	3	0	0
		Trismus	2	0	2
		Muscular weakness	1	0	1
		Rhabdomyolysis	1	0	0
		Musculoskeletal stiffness	1	0	0
		Back pain	3	0	2
		Pain in extremity	1	0	1
		<b>Musculoskeletal and connective tissue disorders</b>	<b>43</b>	<b>0</b>	<b>33</b>
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Langerhans' cell granulomatosis	1	0	1
		Lymphoma	1	0	0
		<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>2</b>	<b>0</b>	<b>1</b>
	Nervous system disorders	Cerebral haemorrhage	1	0	0
		Cerebrovascular disorder	1	0	1
		Drug withdrawal headache	1	0	1
		Headache	43	0	31
		Migraine	3	0	2
		Brain oedema	1	0	1
		Dementia	1	0	0
		Amnesia	6	0	5
		Memory impairment	2	0	2
		Cognitive disorder	1	0	0
		Disturbance in attention	8	0	7
		Chorea	1	0	0
		Akathisia	5	0	3
		Bradykinesia	1	0	1
		Clumsiness	1	0	1
		Dyskinesia	4	0	1
		Extrapyramidal disorder	7	0	6
		Hyperkinesia	5	0	4
		Hypokinesia	3	0	0
		Tardive dyskinesia	3	0	1
		Dystonia	8	0	5
Opisthotonus		1	0	1	
Paresis		1	0	0	
Tremor		48	0	30	
Hyperreflexia		6	0	2	
Ataxia		5	0	3	
Balance disorder		1	0	0	
Coordination abnormal	5	0	4		

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			Case Group	Death Outcomes	Sole	
Reaction Count	Nervous system disorders	Nystagmus	2	0	0	
		Coma	4	0	3	
		Coma hepatic	1	0	1	
		Aphasia	1	0	0	
		Consciousness fluctuating	3	0	1	
		Depressed level of consciousness	4	0	2	
		Lethargy	4	0	3	
		Loss of consciousness	5	0	2	
		Sedation	1	0	0	
		Somnolence	20	0	12	
		Syncope	12	1	6	
		Dizziness	34	0	24	
		Myoclonus	6	0	1	
		Crying	2	0	2	
		Burning sensation	2	0	2	
		Formication	2	0	2	
		Paraesthesia	23	0	20	
		Ageusia	2	0	2	
		Dysgeusia	2	0	2	
		Hypoaesthesia	7	0	6	
		Restless legs syndrome	1	0	1	
		Sensory disturbance	1	0	1	
		Dysarthria	7	0	4	
		Speech disorder	1	0	1	
		Hypertonia	14	0	6	
		Neuroleptic malignant syndrome	4	0	0	
		Serotonin syndrome	35	0	10	
		Muscle contractions involuntary	1	0	1	
		Myasthenic syndrome	2	0	2	
		Neuropathy peripheral	1	0	1	
		Grand mal convulsion	5	0	4	
		Convulsion	23	0	13	
		Epilepsy	1	0	0	
			<b>Nervous system disorders</b>	<b>406</b>	<b>1</b>	<b>247</b>
		Pregnancy, puerperium and perinatal conditions	Intra-uterine death	1	1	0
			Stillbirth	1	1	0
Foetal cardiac disorder	1		1	1		
Foetal disorder	1		1	1		
Foetal distress syndrome	1		0	1		
Pre-eclampsia	1		0	1		
Neonatal disorder	2		0	2		
Meconium stain	1		0	1		

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			Case Group	Death Outcomes	Sole
Reaction Count	Pregnancy, puerperium and perinatal conditions	<b>Pregnancy, puerperium and perinatal conditions</b>	9	4	7
	Psychiatric disorders	Agitation	44	0	29
		Agitation neonatal	1	0	1
		Anxiety	28	0	17
		Nervousness	6	0	3
		Tension	1	0	1
		Fear	1	0	0
		Panic attack	5	0	4
		Panic disorder	1	0	0
		Neurosis	4	0	4
		Restlessness	3	0	3
		Automatism	1	0	0
		Bruxism	8	0	6
		Screaming	1	0	1
		Confusional state	52	0	28
		Disorientation	2	0	2
		Delirium	8	0	2
		Depression	8	0	5
		Depersonalisation	9	0	9
		Dissociation	1	0	0
		Delusion	2	0	2
		Hallucination	25	0	13
		Hallucination, auditory	3	0	2
		Hallucination, visual	2	0	2
		Thinking abnormal	2	0	2
		Eating disorder	1	0	0
		Hypomania	1	0	1
		Mania	10	0	8
		Affect lability	3	0	2
		Anger	2	0	1
		Euphoric mood	1	0	1
		Mood altered	2	0	1
		Mood swings	3	0	2
		Aggression	13	0	6
		Homicidal ideation	5	0	1
		Indifference	1	0	1
		Paranoia	2	0	2
		Violence-related symptom	1	0	0
		Abnormal behaviour	4	0	1
		Hypervigilance	1	0	1
		Mental disorder	1	0	1

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			Case Group	Death Outcomes	Sole		
Reaction Count	Psychiatric disorders	Withdrawal syndrome	12	0	8		
		Acute psychosis	1	0	0		
		Psychotic disorder	2	0	2		
		Anorgasmia	4	0	4		
		Libido decreased	7	0	7		
		Insomnia	18	0	12		
		Sleep attacks	1	0	1		
		Abnormal dreams	1	0	1		
		Abnormal sleep-related event	2	1	0		
		Nightmare	17	0	12		
		Sleep disorder	6	0	5		
		Completed suicide	3	3	1		
		Intentional self-injury	1	0	1		
		Self injurious behaviour	1	0	1		
		Self-injurious ideation	1	0	0		
		Suicidal ideation	16	0	10		
		Suicide attempt	18	0	9		
			<b>Psychiatric disorders</b>	<b>380</b>	<b>4</b>	<b>239</b>	
		Reaction Count	Renal and urinary disorders	Tubulointerstitial nephritis	4	0	2
				Anuria	1	0	0
Renal failure	2			0	2		
Renal failure acute	5			0	1		
Renal impairment	1			0	0		
Renal tubular necrosis	1			0	1		
Urethral disorder	1			0	0		
Dysuria	3			0	2		
Pollakiuria	3			0	2		
Urethral pain	1			0	1		
Urinary hesitation	2			0	1		
Urinary incontinence	3			0	2		
Urinary retention	5			0	4		
Chromaturia	1			0	0		
Haematuria	1			0	1		
Nocturia	1			0	1		
Polyuria	2			0	2		
Renal pain	1			0	0		
	<b>Renal and urinary disorders</b>			<b>38</b>	<b>0</b>	<b>22</b>	
Reaction Count	Reproductive system and breast disorders			Breast enlargement	1	0	1
		Gynaecomastia	1	0	1		
		Breast pain	1	0	1		
		Galactorrhoea	6	0	6		
		Suppressed lactation	1	0	1		

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			Case Group	Death Outcomes	Sole
Reaction Count	Reproductive system and breast disorders	Premenstrual syndrome	1	0	1
		Amenorrhoea	1	0	0
		Penile size reduced	1	0	1
		Penis disorder	1	0	1
		Genital ulceration	1	0	1
		Perineal pain	1	0	1
		Ejaculation delayed	1	0	1
		Ejaculation disorder	1	0	1
		Ejaculation failure	3	0	3
		Erectile dysfunction	9	0	6
		Priapism	1	0	0
		Sexual dysfunction	2	0	2
		Uterine haemorrhage	1	0	1
		Vaginal haemorrhage	1	0	1
		Vulval ulceration	1	0	1
		Vulval erythema	1	0	1
		<b>Reproductive system and breast disorders</b>	<b>37</b>	<b>0</b>	<b>32</b>
	Respiratory, thoracic and mediastinal disorders	Asthma	2	0	1
		Interstitial lung disease	1	0	1
		Pulmonary fibrosis	1	0	1
		Pulmonary hypertension	1	0	0
		Pulmonary embolism	1	1	0
		Apnoea	1	0	1
		Dyspnoea	18	1	11
		Hyperventilation	3	0	3
		Hypoventilation	1	0	1
		Respiratory depression	1	1	0
		Hypoxia	2	1	0
		Cough	9	0	8
		Sputum increased	1	0	1
		Hiccups	1	0	1
		Respiratory failure	1	1	0
Aspiration		1	0	1	
Respiratory disorder		2	0	2	
Dysphonia		1	0	1	
Sneezing		1	0	1	
Snoring		1	0	1	
Throat irritation		1	0	1	
Yawning		3	0	3	
Stridor		1	0	0	
Nasal congestion		1	0	0	
Epistaxis		1	0	1	

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			Case Group	Death Outcomes	Sole
Reaction Count	Respiratory, thoracic and mediastinal disorders	Nasal dryness	1	0	1
		Pharyngeal oedema	1	0	1
<b>Respiratory, thoracic and mediastinal disorders</b>		<b>59</b>	<b>5</b>	<b>42</b>	
	Skin and subcutaneous tissue disorders	Angioedema	5	0	5
		Periorbital oedema	5	0	5
		Urticaria	16	0	16
		Mechanical urticaria	1	0	1
		Blister	2	0	0
		Dry skin	3	0	3
		Skin burning sensation	1	0	1
		Skin discolouration	1	0	1
		Dermatitis	1	0	1
		Drug eruption	1	0	1
		Erythema	2	0	1
		Rash erythematous	5	0	5
		Dermatitis exfoliative	1	0	0
		Exfoliative rash	1	0	1
		Skin exfoliation	1	0	1
		Lichen sclerosus	1	0	0
		Rash papular	1	0	1
		Photosensitivity reaction	1	0	1
		Pruritus	21	0	14
		Rash pruritic	2	0	2
		Psoriasis	1	0	1
		Fixed eruption	1	0	1
		Rash	27	0	19
		Rash generalised	1	0	0
		Rash macular	1	0	0
		Rash maculo-papular	5	0	2
		Erythema nodosum	1	0	1
		Acne	1	0	0
		Alopecia	6	0	3
		Cold sweat	2	0	1
		Hyperhidrosis	43	1	27
		Nail disorder	1	0	1
		Henoch-Schonlein purpura	1	0	1
		Increased tendency to bruise	1	0	1
Purpura	4	0	4		
<b>Skin and subcutaneous tissue disorders</b>	<b>168</b>	<b>1</b>	<b>122</b>		
Social circumstances	Walking disability	1	0	0	
	<b>Social circumstances</b>	<b>1</b>	<b>0</b>	<b>0</b>	

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			Case Group	Death Outcomes	Sole		
Reaction Count	Surgical and medical procedures	Abortion induced	1	1	1		
		Drug therapy changed	12	0	10		
		Therapy regimen changed	6	0	3		
		<b>Surgical and medical procedures</b>	<b>19</b>	<b>1</b>	<b>14</b>		
	Vascular disorders	Peripheral ischaemia	2	0	1		
		Circulatory collapse	5	0	1		
		Hypotension	5	1	3		
		Orthostatic hypotension	4	0	1		
		Deep vein thrombosis	1	1	0		
		Flushing	6	0	4		
		Hot flush	5	0	4		
		Pallor	1	1	0		
		Hypertension	9	0	6		
		Arteritis	1	0	0		
		Vasculitis	1	0	0		
		<b>Vascular disorders</b>	<b>40</b>	<b>3</b>	<b>20</b>		
		<b>Reaction</b>			<b>1961</b>	<b>39</b>	<b>1276</b>