

### Medicine summary (to January 2009- five ATC codes)

Case Count		Case Group	Death	Outcomes	Sole
			16231	217	12140
Reaction Count	Blood and lymphatic system disorders	Anaemia vitamin B12 deficiency	1	0	1
		Iron deficiency anaemia	1	0	1
		Anaemia	36	2	21
		Anaemia macrocytic	1	0	1
		Hypochromic anaemia	3	0	3
		Microcytic anaemia	1	0	1
		Normochromic normocytic anaemia	2	0	1
		Aplastic anaemia	9	4	1
		Bone marrow failure	13	0	7
		Hypoplastic anaemia	1	0	0
		Pancytopenia	38	4	13
		Coagulopathy	7	2	2
		Haemolytic anaemia	7	0	4
		Coombs positive haemolytic anaemia	6	0	2
		Platelet disorder	7	0	6
		Thrombocytosis	3	0	0
		Thrombocytopenia	96	4	45
		Thrombocytopenic purpura	2	0	1
		Macrocytosis	1	0	1
		Red blood cell abnormality	1	0	1
		Lymphadenopathy	22	0	17
		Spleen disorder	1	0	1
		Splenomegaly	2	0	2
		Eosinophilia	33	1	12
		Leukocytosis	22	1	9
		Lymphocytosis	4	0	3
		Monocytosis	1	0	1
		Neutrophilia	3	0	1
		Leukopenia	70	4	37
		Lymphopenia	18	0	10
		Agranulocytosis	68	6	33
		Febrile neutropenia	1	0	1
		Neutropenia	150	4	80
		<b>Blood and lymphatic system disorders</b>	<b>631</b>	<b>32</b>	<b>319</b>
	Cardiac disorders	Atrioventricular block	10	0	4
		Atrioventricular block first degree	1	0	0
		Brugada syndrome	1	1	0
		Bundle branch block	3	0	2
		Bundle branch block bilateral	1	0	0
		Bundle branch block left	1	0	0
		Bundle branch block right	1	0	0
		Conduction disorder	1	0	1
		Arrhythmia	32	4	19
		Bradycardia	58	1	28
		Extrasystoles	25	0	15
		Tachycardia	240	1	140
		Arrhythmia supraventricular	1	0	1
		Atrial fibrillation	29	0	24
		Atrial flutter	2	0	1
		Atrial tachycardia	1	0	1
		Sick sinus syndrome	1	0	1
		Sinus bradycardia	3	0	2
		Sinus tachycardia	7	0	2

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

(1971,1972,1973,1974,1975,1976,1977,1978,1979,1980,1981,1982,1983,1984,1985,1986,1987,1988,1989,1990,1991,1992,1993,1994,1995,1996,1997,1998,1999,2000,2001,2002,2003,2004,2005,2006,2007,2008,2009/Jan)

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Reaction Count		Case Group	Death Outcomes	Sole		
	Cardiac disorders	Supraventricular tachycardia	12	0	7	
		Cardiac arrest	28	10	10	
		Electromechanical dissociation	1	0	0	
		Torsade de pointes	9	1	2	
		Ventricular arrhythmia	1	0	1	
		Ventricular extrasystoles	1	0	1	
		Ventricular fibrillation	6	0	5	
		Ventricular tachycardia	11	1	4	
		Cardiac disorder	2	1	0	
		Cardiovascular insufficiency	1	0	0	
		Carditis	1	0	1	
		Cyanosis	10	2	6	
		Palpitations	291	0	233	
		Aortic valve incompetence	1	0	0	
		Cardiac valve disease	1	0	1	
		Mitral valve incompetence	4	0	1	
		Mitral valve prolapse	1	0	0	
		Coronary artery disease	1	1	0	
		Coronary artery occlusion	1	0	1	
		Coronary artery thrombosis	1	0	0	
		Acute coronary syndrome	1	0	0	
		Acute myocardial infarction	2	0	1	
		Angina pectoris	12	0	8	
		Arteriospasm coronary	2	0	0	
		Myocardial infarction	23	7	12	
		Myocardial ischaemia	1	1	1	
		Cardiac failure	18	4	10	
		Cardiac failure congestive	4	1	3	
		Cardiogenic shock	1	0	0	
		Left ventricular failure	6	1	3	
		Right ventricular failure	1	0	1	
		Cardiomyopathy	27	5	14	
		Congestive cardiomyopathy	1	0	1	
		Atrial hypertrophy	1	0	0	
		Cardiomegaly	5	1	2	
		Dilatation ventricular	2	0	0	
		Left atrial dilatation	1	0	0	
		Ventricular hypokinesia	1	0	0	
		Myocarditis	8	2	0	
		Pericarditis	2	0	1	
		Pericardial effusion	1	0	0	
		<b>Cardiac disorders</b>	<b>922</b>	<b>45</b>	<b>571</b>	
		Congenital, familial and genetic disorders	Pulmonary artery stenosis congenital	1	0	1
			Heart disease congenital	9	1	7
	Ventricular hypoplasia		1	1	1	
	Atrial septal defect		1	0	1	
	Cardiac septal defect		1	0	1	
	Ventricular septal defect		4	0	3	
	Coarctation of the aorta		2	0	2	
	Transposition of the great vessels		1	0	1	
	Falot's tetralogy		1	0	0	
	Patent ductus arteriosus		1	0	1	
	Vascular malformation peripheral		2	0	1	
	Trisomy 18		1	0	1	

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**Medicine summary (to January 2009- five ATC codes)**

Reaction Count		Case Group	Death Outcomes	Sole	
Congenital, familial and genetic disorders	Trisomy 21	2	0	1	
	Cytogenetic abnormality	2	0	2	
	Congenital anomaly	2	1	2	
	Hemihypertrophy	2	0	2	
	Multiple congenital abnormalities	14	1	8	
	Congenital eye disorder	1	0	1	
	Anal atresia	1	0	0	
	Exomphalos	1	0	1	
	Gastrointestinal malformation	1	0	0	
	Hernia congenital	2	0	1	
	Oesophageal atresia	1	0	0	
	Cleft palate	3	0	2	
	Cleft lip	1	0	1	
	Pierre Robin syndrome	2	0	2	
	Congenital foot malformation	2	0	1	
	Congenital hand malformation	4	0	2	
	Limb malformation	1	0	0	
	Limb reduction defect	3	0	3	
	Polydactyly	2	0	2	
	Syndactyly	3	0	1	
	Talipes	5	0	4	
	Microcephaly	1	0	1	
	Congenital musculoskeletal anomaly	1	0	0	
	Dysmorphism	2	0	2	
	Meningomyelocele	1	0	1	
	Cerebellar hypoplasia	1	1	1	
	Cerebral palsy	2	0	1	
	Congenital brain damage	4	0	4	
	Congenital hydrocephalus	2	0	2	
	Congenital neurological disorder	1	1	1	
	Tourette's disorder	3	0	3	
	Kidney malformation	1	0	0	
	Renal aplasia	1	0	1	
	Hypospadias	1	0	0	
	Pulmonary malformation	2	0	2	
	<b>Congenital, familial and genetic disorders</b>	<b>103</b>	<b>6</b>	<b>75</b>	
	Ear and labyrinth disorders	Ear pain	9	0	7
		Deafness	30	0	22
		Deafness neurosensory	1	0	1
		Deafness unilateral	1	0	1
		Hearing impaired	4	0	4
		Hypoacusis	1	0	0
		Hyperacusis	16	0	15
		Inner ear disorder	4	0	4
		Motion sickness	2	0	2
		Tinnitus	141	0	121
		Vertigo	108	0	85
Vertigo positional		1	0	1	
Eustachian tube obstruction		1	0	1	
Otosclerosis		1	0	1	
Tympanic membrane hyperaemia		1	0	0	
<b>Ear and labyrinth disorders</b>		<b>321</b>	<b>0</b>	<b>265</b>	
Endocrine disorders		Cushing's syndrome	2	0	0
	Adrenal insufficiency	1	1	0	

Outcome Description

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**Medicine summary (to January 2009- five ATC codes)**

Reaction Count		Case Group	Death Outcomes	Sole	
Endocrine disorders	Hyperprolactinaemia	37	0	28	
	Diabetes insipidus	1	0	1	
	Inappropriate antidiuretic hormone secretion	115	2	86	
	Hyperparathyroidism	2	0	1	
	Thyroiditis	1	0	1	
	Goitre	3	0	3	
	Thyroid disorder	1	0	1	
	Hyperthyroidism	6	0	4	
	Hypothyroidism	10	0	4	
	<b>Endocrine disorders</b>	<b>179</b>	<b>3</b>	<b>129</b>	
	Eye disorders	Cataract	7	0	3
		Corneal opacity	1	0	1
		Keratopathy	1	0	0
		Xerophthalmia	11	0	9
		Pigment dispersion syndrome	1	0	1
		Dry eye	5	0	5
		Lacrimonal disorder	10	0	7
		Lacrimation increased	2	0	1
		Eye disorder	4	0	4
		Eye pain	27	0	19
		Eye swelling	4	0	4
		Ocular discomfort	3	0	3
		Retinal disorder	3	0	3
		Angle closure glaucoma	2	0	2
		Glaucoma	32	0	27
Open angle glaucoma		1	0	1	
Hyphaema		1	0	1	
Conjunctival haemorrhage		3	0	3	
Optic ischaemic neuropathy		1	0	1	
Conjunctivitis		25	0	16	
Keratitis		2	0	2	
Ulcerative keratitis		1	0	1	
Ocular hyperaemia		3	0	2	
Blepharospasm		5	0	4	
Eyelid ptosis		2	0	2	
Eye movement disorder		2	0	2	
Oculogyric crisis		20	0	14	
Strabismus		2	0	2	
Miosis		3	0	1	
Mydriasis		73	0	49	
Pupil fixed		1	0	1	
Pupillary reflex impaired		2	0	0	
Abnormal sensation in eye		2	0	2	
Eye rolling		5	0	1	
Eyelid sensory disorder	1	0	1		
Photophobia	34	0	24		
Myodesopsia	1	0	1		
Vitreous detachment	1	0	1		
Papilloedema	2	0	0		
Macular degeneration	1	0	0		
Retinal degeneration	1	0	0		
Exophthalmos	2	0	2		
Retinal haemorrhage	2	0	1		
Blindness	5	0	4		

Outcome Description

(Causality possible,Causality probable,Causality certain)

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Case Group

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Reaction Count		Case Group	Death Outcomes	Sole	
Eye disorders	Blindness transient	1	0	1	
	Night blindness	2	0	2	
	Sudden visual loss	1	0	1	
	Visual acuity reduced	5	0	4	
	Accommodation disorder	27	0	23	
	Myopia	1	0	1	
	Chromatopsia	1	0	1	
	Xanthopsia	1	0	1	
	Diplopia	36	0	28	
	Photopsia	6	0	6	
	Scintillating scotoma	1	0	1	
	Vision blurred	59	1	44	
	Visual impairment	309	1	243	
	Scotoma	4	0	1	
	Optic neuropathy	1	0	0	
	<b>Eye disorders</b>	<b>772</b>	<b>2</b>	<b>585</b>	
	Gastrointestinal disorders	Abdominal hernia	1	0	1
		Hiatus hernia	1	0	1
		Anorectal disorder	1	0	1
		Proctalgia	1	0	1
Anal inflammation		1	0	1	
Anal pruritus		1	0	1	
Rectal discharge		1	0	1	
Rectal tenesmus		3	0	3	
Dental caries		9	0	6	
Tooth malformation		1	0	1	
Tooth disorder		7	0	4	
Sensitivity of teeth		2	0	2	
Toothache		5	0	4	
Tooth discolouration		5	0	2	
Gingival atrophy		2	0	1	
Gingival hyperplasia		4	0	3	
Gingivitis		12	0	12	
Gingival bleeding		5	0	4	
Pancreatitis		17	0	10	
Pancreatitis acute		3	0	1	
Gastric disorder		1	0	1	
Gastrointestinal disorder		5	0	4	
Barrett's oesophagus		1	0	1	
Hyperchlorhydria		1	0	1	
Gastric haemorrhage		1	0	0	
Anal haemorrhage		1	0	1	
Rectal haemorrhage		19	0	15	
Gastrointestinal haemorrhage		14	3	3	
Haematemesis		21	3	8	
Melaena		16	2	2	
Upper gastrointestinal haemorrhage		1	0	1	
Colitis		9	0	8	
Colitis ulcerative		2	1	1	
Gastritis		11	1	7	
Crohn's disease	1	0	1		
Enteritis	2	0	1		
Oesophagitis	13	0	9		
Reflux oesophagitis	7	0	5		

Outcome Description

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Suspect Type

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Case Group

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count	Gastrointestinal disorders	Case Group	Death Outcomes	Sole
	Proctitis	3	0	2
	Diarrhoea	632	4	539
	Diarrhoea haemorrhagic	2	0	2
	Diarrhoea neonatal	1	0	1
	Constipation	156	1	117
	Gastroesophageal reflux disease	11	0	9
	Impaired gastric emptying	1	0	0
	Bowel movement irregularity	1	0	1
	Gastrointestinal motility disorder	1	0	1
	Frequent bowel movements	1	0	1
	Irritable bowel syndrome	3	0	3
	Oesophageal spasm	5	0	5
	Ileus paralytic	7	0	2
	Gastrointestinal sounds abnormal	1	0	1
	Dyspepsia	107	1	95
	Epigastric discomfort	1	0	1
	Eructation	14	0	11
	Abnormal faeces	2	0	2
	Faeces discoloured	4	0	4
	Faeces pale	1	0	1
	Abdominal distension	16	0	12
	Flatulence	55	0	46
	Abdominal pain	294	1	222
	Abdominal pain lower	2	0	2
	Abdominal pain upper	27	0	25
	Infantile colic	1	0	1
	Oesophageal pain	1	0	1
	Abdominal discomfort	12	0	11
	Breath odour	4	0	2
	Dysphagia	83	0	58
	Faecal incontinence	16	0	13
	Nausea	1541	2	1294
	Retching	7	0	7
	Vomiting	573	5	425
	Vomiting in pregnancy	1	0	1
	Vomiting neonatal	3	0	3
	Ileus	3	0	1
	Intestinal obstruction	12	1	5
	Oesophageal stenosis	1	0	0
	Duodenal ulcer	9	0	1
	Duodenal ulcer haemorrhage	7	1	1
	Duodenal ulcer perforation	4	2	0
	Gastric ulcer	4	0	0
	Gastric ulcer haemorrhage	4	0	1
	Gastric ulcer perforation	1	0	0
	Gastritis erosive	1	0	0
	Intestinal perforation	2	1	1
	Oesophagitis ulcerative	3	0	0
	Peptic ulcer	2	1	1
	Peptic ulcer haemorrhage	1	0	1
	Peptic ulcer perforation	3	2	0
	Gastrointestinal necrosis	1	1	0
	Celiac disease	1	0	1
	Malabsorption	1	0	0

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

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**Medicine summary (to January 2009- five ATC codes)**

Reaction Count		Case Group	Death Outcomes	Sole	
Gastrointestinal disorders	Chapped lips	1	0	1	
	Cheilitis	7	0	6	
	Lip oedema	2	0	2	
	Lip swelling	11	0	5	
	Palatal disorder	1	0	1	
	Paraesthesia oral	1	0	1	
	Hypoaesthesia oral	4	0	4	
	Oral discomfort	1	0	1	
	Oral mucosal exfoliation	1	0	0	
	Palatal oedema	1	0	1	
	Aphthous stomatitis	2	0	2	
	Mouth ulceration	63	1	53	
	Stomatitis	16	0	12	
	Ascites	6	3	2	
	Peritonitis	1	1	0	
	Retroperitoneal fibrosis	3	0	0	
	Aptyalism	1	0	1	
	Dry mouth	281	1	227	
	Lip dry	1	0	1	
	Saliva altered	2	0	2	
	Salivary hypersecretion	34	1	22	
	Salivary gland enlargement	5	0	3	
	Glossitis	28	0	22	
	Tongue disorder	10	0	9	
	Tongue ulceration	9	0	6	
	Glossodynia	1	0	1	
	Swollen tongue	14	0	10	
	Tongue blistering	1	0	0	
	Tongue discolouration	5	0	3	
	Tongue oedema	40	0	31	
		<b>Gastrointestinal disorders</b>	<b>4411</b>	<b>40</b>	<b>3492</b>
	General disorders and administration site conditions	Application site reaction	2	0	1
		Hyperthermia	1	0	1
		Hyperthermia malignant	3	0	2
		Hypothermia	14	2	7
		Temperature regulation disorder	1	0	1
		Fever neonatal	3	0	2
		Hyperpyrexia	4	1	1
		Pyrexia	323	4	191
		Death	12	12	4
		Death neonatal	2	1	2
		Sudden death	51	51	11
		Asthenia	175	2	122
		Chronic fatigue syndrome	1	0	1
		Fatigue	412	1	313
		Malaise	277	4	195
		Abasia	2	0	1
		Gait disturbance	90	0	58
Concomitant disease aggravated		1	0	1	
Condition aggravated		12	0	8	
Developmental delay		2	0	2	
Energy increased		2	0	1	
General physical health deterioration		1	0	1	
Influenza like illness	38	0	30		

Outcome Description

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Reaction Count		Case Group	Death Outcomes	Sole	
	General disorders and administration site conditions	Irritability	46	0	39
		Local swelling	1	0	1
		Multi-organ failure	1	1	0
		Secretion discharge	1	0	1
		Swelling	2	0	2
		Enanthema	1	0	0
		Mucosal inflammation	1	0	0
		Face oedema	101	0	76
		Generalised oedema	14	0	11
		Gravitational oedema	50	0	31
		Oedema	74	1	51
		Oedema peripheral	112	0	93
		Chest pain	178	0	129
		Discomfort	1	0	1
		Facial pain	1	0	0
		Pain	124	1	100
		Chest discomfort	15	0	11
		Chills	132	1	87
		Feeling abnormal	39	2	37
		Feeling cold	8	0	4
		Feeling hot	13	0	8
		Feeling jittery	9	0	7
		Feeling of body temperature change	10	0	9
		Hangover	1	0	1
		Hunger	2	0	2
		Sensation of foreign body	1	0	1
		Thirst	35	0	23
		Alcohol interaction	2	1	0
		Drug interaction	41	3	0
		Drug effect decreased	6	0	5
		Drug ineffective	272	10	222
		Drug tolerance increased	2	1	1
		Paradoxical drug reaction	3	0	1
		Therapeutic response decreased	12	0	8
		Therapeutic response increased	1	0	0
		Therapeutic response unexpected	21	0	20
		Therapeutic response unexpected with drug substitution	26	0	26
		Therapeutic product ineffective for unapproved indication	1	0	1
		Drug withdrawal syndrome	74	0	69
		Drug withdrawal syndrome neonatal	38	0	29
		Rebound effect	1	0	1
		Impaired healing	1	0	1
		<b>General disorders and administration site conditions</b>	<b>2903</b>	<b>99</b>	<b>2065</b>
	Hepatobiliary disorders	Biliary colic	2	0	2
		Cholangitis	1	0	1
		Vanishing bile duct syndrome	1	0	1
		Cholecystitis	5	0	2
		Cholelithiasis	5	0	4
		Cholestasis	3	0	2
		Hepatitis cholestatic	38	0	27
		Hyperbilirubinaemia	3	0	1
		Jaundice	108	8	60
		Jaundice cholestatic	2	0	2
		Liver disorder	1	0	1

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Reaction Count		Case Group	Death Outcomes	Sole
Hepatobiliary disorders	Hepatic function abnormal	326	5	173
	Hepatic failure	22	12	7
	Hepatic cirrhosis	4	2	0
	Hepatomegaly	11	0	5
	Hepatosplenomegaly	4	1	1
	Liver tenderness	1	0	1
	Autoimmune hepatitis	1	0	0
	Hepatic necrosis	3	3	1
	Hepatic steatosis	6	1	2
	Hepatitis	111	6	52
	Hepatitis chronic active	1	0	1
	Hepatitis fulminant	1	0	0
	Hepatocellular injury	19	1	6
	Hepatotoxicity	2	0	1
	<b>Hepatobiliary disorders</b>	<b>681</b>	<b>39</b>	<b>353</b>
Immune system disorders	Hypersensitivity	20	0	16
	Serum sickness	4	0	4
	Drug hypersensitivity	1	0	1
	Anaphylactic reaction	5	0	4
	Anaphylactic shock	2	0	2
	Anaphylactoid reaction	10	0	7
	Hypogammaglobulinaemia	1	0	1
<b>Immune system disorders</b>	<b>43</b>	<b>0</b>	<b>35</b>	
Infections and infestations	Bacterial infection	2	0	0
	Cellulitis	7	0	4
	Folliculitis	3	0	2
	Pyomyositis	1	0	1
	Candidiasis	6	0	2
	Genital candidiasis	1	0	1
	Oesophageal candidiasis	1	0	0
	Oral candidiasis	1	0	0
	Fungal infection	1	0	0
	Diverticulitis	2	0	2
	Gastroenteritis	1	0	1
	Mastitis	3	0	2
	Meningitis	3	1	2
	Meningitis aseptic	1	0	0
	Abscess of salivary gland	1	0	1
	Labyrinthitis	1	0	0
	Otitis externa	1	0	0
	Otitis media	2	0	1
	Vaginal infection	9	0	7
	Abscess	3	0	2
	Infection	5	0	4
	Bronchitis	1	0	1
	Lower respiratory tract infection	1	0	1
	Pneumonia	28	10	11
	Orchitis	1	0	1
	Sepsis	21	9	6
	Furuncle	3	0	3
Rash pustular	11	0	8	
Laryngitis	2	0	2	
Nasopharyngitis	3	0	2	
Pharyngitis	43	0	28	

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

(1971,1972,1973,1974,1975,1976,1977,1978,1979,1980,1981,1982,1983,1984,1985,1986,1987,1988,1989,1990,1991,1992,1993,1994,1995,1996,1997,1998,1999,2000,2001,2002,2003,2004,2005,2006,2007,2008,2009/Jan)

**Medicine summary (to January 2009- five ATC codes)**

Reaction Count		Case Group	Death Outcomes	Sole
Infections and infestations	Rhinitis	27	0	23
	Sinusitis	4	0	4
	Upper respiratory tract infection	3	0	3
	Cystitis	5	0	4
	Urinary tract infection	14	0	11
	Lymphangitis	1	0	1
	Herpes simplex	8	0	8
	Herpes zoster	2	0	2
	Influenza	4	0	3
	Gastritis viral	1	0	1
	Gastroenteritis viral	1	0	1
	Viral infection	1	0	0
	<b>Infections and infestations</b>	<b>240</b>	<b>20</b>	<b>156</b>
	Injury, poisoning and procedural complications	Limb injury	1	0
Drug toxicity		7	5	2
Poisoning		1	0	1
Therapeutic agent toxicity		2	0	0
Drug exposure before pregnancy		1	0	1
Drug exposure during pregnancy		59	5	43
Maternal drugs affecting foetus		1	1	1
Subdural haemorrhage		1	0	1
Fall		50	0	21
Road traffic accident		1	0	0
Wound haemorrhage		1	0	0
Uterine injury		1	0	1
Face injury		1	0	0
Head injury		2	0	0
Contusion		25	0	20
Chillblains		3	0	2
Heat stroke		2	1	1
Sunburn		1	0	1
Drug administration error		1	0	1
Inappropriate schedule of drug administration		1	0	1
Drug prescribing error		2	0	0
Medication error		15	0	10
Drug exposure via breast milk		2	0	2
Accidental overdose		4	0	3
Intentional overdose		20	3	13
Multiple drug overdose intentional		1	0	0
Overdose		29	1	15
Post procedural haemorrhage		2	0	2
<b>Injury, poisoning and procedural complications</b>	<b>237</b>	<b>16</b>	<b>142</b>	
Investigations	Cardiac murmur	1	0	1
	Echocardiogram abnormal	1	0	0
	Ejection fraction decreased	3	0	0
	Electrocardiogram QT interval	2	0	2
	Electrocardiogram QT prolonged	29	2	12
	Electrocardiogram ST segment abnormal	1	0	1
	Electrocardiogram ST segment depression	1	0	1
	Electrocardiogram ST segment elevation	1	0	1
	Electrocardiogram T wave inversion	1	0	0
	Electrocardiogram abnormal	21	1	8
	QRS axis abnormal	1	0	0
	Heart rate decreased	1	0	0

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count	Investigations	Case Group	Death Outcomes	Sole
	Heart rate increased	12	0	10
	Blood pressure decreased	8	0	6
	Blood pressure increased	32	0	26
	Blood pressure systolic decreased	1	0	1
	Glucocorticoids increased	1	0	0
	Blood prolactin increased	4	0	1
	Blood thyroid stimulating hormone decreased	1	0	1
	Blood testosterone decreased	1	0	0
	Blood testosterone increased	1	0	0
	Thyroid function test abnormal	2	0	2
	Blood creatine phosphokinase increased	67	4	19
	Troponin I increased	1	0	0
	Troponin increased	4	0	1
	Blood alkaline phosphatase increased	5	0	3
	Blood lactate dehydrogenase increased	2	0	1
	Blood amylase increased	3	0	0
	Lipase increased	2	0	0
	Bleeding time prolonged	10	0	8
	International normalised ratio decreased	1	0	0
	International normalised ratio increased	6	0	0
	Prothrombin level decreased	31	0	6
	Prothrombin level increased	2	0	0
	Prothrombin time prolonged	1	0	0
	Red blood cell sedimentation rate increased	20	0	11
	Platelet adhesiveness decreased	2	0	1
	Platelet aggregation abnormal	2	0	0
	Platelet count decreased	2	0	2
	Eosinophil count increased	1	0	0
	Lymphocyte count decreased	1	0	1
	Neutrophil count decreased	2	0	1
	Neutrophil count increased	2	0	0
	White blood cell count decreased	3	0	2
	White blood cell count increased	5	0	0
	Alanine aminotransferase increased	6	0	3
	Ammonia increased	1	0	0
	Aspartate aminotransferase increased	6	0	4
	Blood bilirubin increased	2	0	1
	Gamma-glutamyltransferase increased	9	0	4
	Hepatic enzyme abnormal	1	0	1
	Hepatic enzyme increased	5	0	4
	Liver function test abnormal	56	1	35
	Transaminases increased	1	0	1
	Antinuclear antibody increased	1	0	1
	Antinuclear antibody positive	8	0	6
	Immunoglobulins decreased	1	0	0
	Laboratory test abnormal	1	0	1
	Blood cholesterol increased	7	0	2
	Total cholesterol/HDL ratio decreased	1	0	0
	Lipids abnormal	1	0	0
	Blood triglycerides increased	4	0	1
	Oxygen saturation decreased	1	0	1
	Blood glucose decreased	2	0	1
	Blood glucose increased	5	0	4
	Blood folate abnormal	1	0	0

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

(1971,1972,1973,1974,1975,1976,1977,1978,1979,1980,1981,1982,1983,1984,1985,1986,1987,1988,1989,1990,1991,1992,1993,1994,1995,1996,1997,1998,1999,2000,2001,2002,2003,2004,2005,2006,2007,2008,2009/Jan)

### Medicine summary (to January 2009- five ATC codes)

Reaction Count	Investigations	Case Group	Death Outcomes	Sole	
		Blood folate decreased	1	0	1
		CSF pressure increased	1	0	1
		Electroencephalogram abnormal	4	0	1
		Nerve conduction studies abnormal	1	0	1
		Intraocular pressure increased	2	0	2
		Apgar score low	4	0	4
		Body temperature decreased	2	0	1
		Body temperature fluctuation	1	0	1
		Body temperature increased	5	0	1
		Respiratory rate increased	1	0	0
		Weight decreased	128	3	92
		Weight increased	237	2	195
		Blood albumin decreased	1	0	1
		Blood albumin increased	1	0	0
		C-reactive protein increased	8	0	5
		Globulins increased	2	0	2
		Blood creatinine decreased	1	0	1
		Blood creatinine increased	3	0	2
		Creatinine renal clearance decreased	2	0	0
		Blood urine present	1	0	0
		Urine analysis abnormal	11	0	8
		Urine output decreased	1	0	1
		Semen analysis abnormal	4	0	4
		Sperm count decreased	1	0	0
		Spermatozoa abnormal	1	0	1
		Anticonvulsant drug level decreased	1	0	0
		Antidepressant drug level above therapeutic	1	0	1
		Antipsychotic drug level increased	1	0	0
		Drug level above therapeutic	5	0	0
		Drug level decreased	8	0	0
		Drug level increased	60	8	2
		Blood phosphorus decreased	2	0	1
		Blood sodium decreased	6	0	5
		Serum ferritin increased	2	0	2
		Blood electrolytes abnormal	2	0	2
		Blood osmolarity decreased	4	0	3
		Urine osmolarity decreased	1	0	0
		<b>Investigations</b>	<b>938</b>	<b>21</b>	<b>540</b>
	Metabolism and nutrition disorders	Ketosis	2	0	1
		Lactic acidosis	1	1	0
		Metabolic acidosis	2	0	1
		Alkalosis	1	0	0
		Acidosis	11	2	3
		Decreased appetite	242	5	193
		Food craving	1	0	1
		Hypophagia	2	0	1
		Increased appetite	51	0	44
		Abnormal weight gain	1	0	1
		Failure to thrive	1	0	1
		Feeding disorder neonatal	13	0	11
		Obesity	2	0	1
		Weight loss poor	1	0	1
		Hypercalcaemia	2	0	0
		Hypocalcaemia	7	1	1

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

(1971,1972,1973,1974,1975,1976,1977,1978,1979,1980,1981,1982,1983,1984,1985,1986,1987,1988,1989,1990,1991,1992,1993,1994,1995,1996,1997,1998,1999,2000,2001,2002,2003,2004,2005,2006,2007,2008,2009/Jan)

### Medicine summary (to January 2009- five ATC codes)

Reaction Count		Case Group	Death Outcomes	Sole	
Metabolism and nutrition disorders	Tetany	17	0	13	
	Hypermagnesaemia	1	0	1	
	Hypomagnesaemia	4	1	1	
	Hypophosphataemia	2	0	1	
	Hyperchloraemia	2	1	0	
	Hypochloraemia	9	1	4	
	Electrolyte imbalance	4	0	3	
	Oligodipsia	1	0	1	
	Polydipsia	11	0	9	
	Hyperkalaemia	13	1	3	
	Hypokalaemia	49	3	14	
	Hypernatraemia	12	0	8	
	Hyponatraemia	604	6	375	
	Dehydration	44	0	26	
	Hypovolaemia	1	0	0	
	Fluid retention	9	0	8	
	Alcohol intolerance	20	0	12	
	Lactose intolerance	1	0	1	
	Diabetes mellitus	19	0	11	
	Diabetes mellitus inadequate control	2	0	1	
	Gestational diabetes	1	0	1	
	Type 2 diabetes mellitus	1	0	0	
	Glucose tolerance impaired	1	0	1	
	Hyperglycaemia	31	0	22	
	Hyperinsulinaemia	2	0	2	
	Hypoglycaemia	39	0	23	
	Hypoglycaemia neonatal	4	0	3	
	Iron deficiency	1	0	1	
	Hypercholesterolaemia	7	0	6	
	Hypertriglyceridaemia	3	0	2	
	Hyperlipidaemia	8	0	6	
	Hypoproteinaemia	1	0	0	
	Gout	7	0	6	
	Hyperuricaemia	2	0	1	
	<b>Metabolism and nutrition disorders</b>	<b>1273</b>	<b>22</b>	<b>826</b>	
	Musculoskeletal and connective tissue disorders	Exostosis	1	0	1
		Jaw disorder	2	0	2
		Bone pain	9	0	8
		Pain in jaw	4	0	4
		Osteoporosis	3	0	2
		Collagen disorder	2	0	2
		Scleroderma	3	0	3
		Sjogren's syndrome	1	0	1
		Systemic lupus erythematosus	10	0	4
Pathological fracture		1	0	0	
Arthritis		42	0	33	
Arthropathy		1	0	1	
Polyarthritis		3	0	3	
Temporomandibular joint syndrome		1	0	1	
Arthralgia		225	0	188	
Joint stiffness		3	0	2	
Joint swelling		11	0	9	
Osteoarthritis		23	0	19	
Myositis		4	1	1	

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count		Case Group	Death Outcomes	Sole	
	Musculoskeletal and connective tissue disorders	Myalgia	293	0	226
		Muscle atrophy	1	0	1
		Muscle disorder	2	0	2
		Muscle fatigue	1	0	1
		Muscle spasms	77	0	57
		Muscle tightness	6	0	5
		Muscle twitching	190	0	147
		Hypertonia neonatal	3	0	2
		Hypotonia neonatal	5	0	4
		Muscle rigidity	18	0	6
		Nuchal rigidity	1	0	0
		Torticollis	6	0	3
		Trismus	16	0	14
		Muscular weakness	21	0	13
		Myopathy	8	1	3
		Rhabdomyolysis	25	2	6
		Limb deformity	1	0	1
		Mobility decreased	8	0	2
		Musculoskeletal stiffness	18	0	7
		Sensation of heaviness	3	0	2
		Back pain	50	0	34
		Musculoskeletal chest pain	1	0	0
		Musculoskeletal pain	1	0	0
		Neck pain	6	0	5
		Pain in extremity	11	0	10
		Bursitis	5	0	5
		Synovitis	2	0	2
		Tendonitis	1	0	1
		Tenosynovitis	1	0	1
		<b>Musculoskeletal and connective tissue disorders</b>	<b>1130</b>	<b>4</b>	<b>844</b>
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	1	0	1
		Breast cancer female	2	0	0
		Breast cancer male	1	0	1
		Breast neoplasm	1	0	1
		Prolactin-producing pituitary tumour	1	0	1
		Colon cancer	1	0	0
		Gastric cancer	1	1	1
		Gastrointestinal carcinoma	1	0	0
		Pseudolymphoma	3	1	0
		Langerhans' cell granulomatosis	1	0	1
		Hepatic neoplasm malignant	1	1	1
		Leukaemia	1	0	0
		Acute leukaemia	2	0	0
		Hairy cell leukaemia	1	0	0
		Leukaemia granulocytic	1	0	0
		Lymphoma	2	0	1
		Angiocentric lymphoma	1	1	0
		Metastases to bone marrow	1	1	0
		Metastasis	1	0	1
		Neoplasm malignant	1	0	1
		Brain neoplasm benign	1	0	1
		Paraproteinaemia	1	0	1
		Bronchioloalveolar carcinoma	1	1	0
		Sarcoma	2	0	2

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

(1971,1972,1973,1974,1975,1976,1977,1978,1979,1980,1981,1982,1983,1984,1985,1986,1987,1988,1989,1990,1991,1992,1993,1994,1995,1996,1997,1998,1999,2000,2001,2002,2003,2004,2005,2006,2007,2008,2009/Jan)

### Medicine summary (to January 2009- five ATC codes)

Reaction Count	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Case Group	Death Outcomes	Sole
	<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>30</b>	<b>6</b>	<b>14</b>
	Nervous system disorders			
	Cerebellar infarction	1	0	0
	Cerebral haemorrhage	13	3	4
	Cerebrovascular accident	9	0	6
	Haemorrhage intracranial	4	0	1
	Haemorrhagic stroke	2	0	2
	Subarachnoid haemorrhage	1	1	0
	Cerebrovascular disorder	17	3	11
	Vertebral artery stenosis	1	0	0
	Transient ischaemic attack	3	0	1
	Facial palsy	6	0	6
	Facial spasm	1	0	0
	Tongue paralysis	2	0	1
	Anosmia	2	0	1
	Parosmia	11	0	9
	Encephalopathy	26	6	12
	Encephalopathy neonatal	1	0	1
	Hypertensive encephalopathy	3	0	3
	Hypoxic encephalopathy	1	0	1
	Drug withdrawal headache	3	0	3
	Headache	894	3	725
	Tension headache	3	0	2
	Migraine	63	0	46
	Migraine with aura	1	0	1
	Benign intracranial hypertension	1	0	1
	Brain oedema	5	2	2
	Intracranial pressure increased	1	0	1
	Dementia	9	0	0
	Autism	2	0	2
	Amnesia	164	0	118
	Memory impairment	16	0	7
	Cognitive disorder	15	0	7
	Disturbance in attention	111	2	90
	Mental impairment	11	0	10
	Mental retardation	1	0	1
	Chorea	1	0	0
	Choreoathetosis	19	0	14
	Akathisia	90	4	59
	Akinesia	1	0	1
	Bradykinesia	7	0	5
	Clumsiness	3	0	3
	Dyskinesia	132	0	85
	Dyskinesia neonatal	1	0	0
	Extrapyramidal disorder	84	3	47
	Hyperkinesia	133	0	103
	Hypokinesia	25	0	14
	Movement disorder	4	0	3
	Psychomotor hyperactivity	10	0	8
	Tardive dyskinesia	44	0	21
	Dystonia	158	0	103
	Opisthotonus	9	0	3
	Gait spastic	1	0	1
	Hemiparesis	11	0	6
	Hemiplegia	1	0	1

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants,Selective serotonin reuptake inhibitors,Non-selective monoamine reuptake inhibitors,Monoamine oxidase A inhibitors,Monoamine oxidase inhibitors,non-selective)

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count	Nervous system disorders		Case Group	Death Outcomes	Sole
		Monoplegia	1	0	1
		Paralysis	13	0	12
		Paresis	18	0	14
		Quadriplegia	1	0	0
		Cogwheel rigidity	5	0	2
		Masked facies	1	0	0
		Parkinson's disease	1	0	1
		Parkinsonian gait	1	0	0
		Parkinsonian rest tremor	1	0	0
		Parkinsonism	10	0	4
		Asterixis	1	0	0
		Tremor	783	3	569
		Tremor neonatal	3	0	2
		Hyperreflexia	47	0	16
		Hyporeflexia	5	0	4
		Reflexes abnormal	3	0	2
		Ataxia	192	1	132
		Balance disorder	17	0	9
		Cerebellar syndrome	5	0	2
		Coordination abnormal	69	0	45
		Dysstasia	3	0	3
		Nystagmus	22	0	8
		Coma	52	4	20
		Coma hepatic	1	0	1
		Diabetic coma	1	0	0
		Aphasia	25	0	17
		Altered state of consciousness	2	1	0
		Consciousness fluctuating	24	1	5
		Depressed level of consciousness	18	0	6
		Lethargy	53	0	39
		Loss of consciousness	32	1	19
		Sedation	21	0	12
		Somnolence	486	3	360
		Somnolence neonatal	2	0	2
		Stupor	14	0	11
		Syncope	233	5	143
		Central nervous system lesion	1	0	0
		Motor dysfunction	1	0	1
		Nervous system disorder	1	1	1
		Clonus	10	0	3
		Dizziness	950	1	760
		Dizziness postural	2	0	1
		Drooling	1	0	0
		Head discomfort	2	0	2
		Meningism	6	0	4
		Myoclonus	31	0	11
		Neurological symptom	2	0	1
		Presyncope	5	0	5
		Tongue biting	1	0	0
		Unresponsive to stimuli	1	0	0
		Crying	28	0	24
		Burning sensation	9	0	9
		Formication	8	0	8
		Hyperaesthesia	22	0	18

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count		Case Group	Death Outcomes	Sole
	Nervous system disorders	Paraesthesia	436	0 372
		Ageusia	13	0 10
		Aura	1	0 0
		Dysgeusia	68	0 54
		Hypoaesthesia	127	0 106
		Neuralgia	5	0 5
		Restless legs syndrome	27	0 27
		Sensory disturbance	46	0 37
		Sensory loss	2	0 2
		Dysarthria	84	0 54
		Incoherent	5	0 2
		Repetitive speech	1	0 0
		Speech disorder	70	0 46
		Hemianopia	3	0 1
		Tunnel vision	2	0 2
		Visual field defect	12	0 11
		Adrenergic syndrome	1	0 0
		Anticholinergic syndrome	5	0 3
		Autonomic nervous system imbalance	2	0 0
		Autonomic neuropathy	1	0 0
		Cholinergic syndrome	1	0 0
		Horner's syndrome	1	0 1
		Hypertonia	201	2 117
		Hypotonia	9	0 8
		Neuroleptic malignant syndrome	50	3 9
		Serotonin syndrome	275	1 86
		Muscle contractions involuntary	10	0 6
		Muscle spasticity	1	0 0
		Myasthenia gravis	1	0 0
		Myasthenic syndrome	4	0 4
		Guillain-Barre syndrome	1	0 0
		Peroneal nerve palsy	1	0 1
		Neuritis	4	0 3
		Neuropathy peripheral	31	0 20
		Petit mal epilepsy	3	0 2
		Convulsion neonatal	9	0 6
		Grand mal convulsion	118	1 64
		Temporal lobe epilepsy	1	0 0
		Convulsion	419	4 260
		Convulsions local	2	0 1
		Convulsive threshold lowered	2	0 1
		Drug withdrawal convulsions	5	0 2
		Epilepsy	13	0 9
		Status epilepticus	2	0 2
		Tonic clonic movements	1	0 1
		Tonic convulsion	3	0 2
		Sleep paralysis	2	0 1
		Circadian rhythm sleep disorder	1	0 0
		Hypersomnia	5	0 3
		Narcolepsy	1	0 0
		Poor quality sleep	11	1 9
		Nerve root lesion	1	0 1
		<b>Nervous system disorders</b>	<b>7485</b>	<b>60 5212</b>
	Pregnancy, puerperium and perinatal conditions	Abortion	5	0 5

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

(1971,1972,1973,1974,1975,1976,1977,1978,1979,1980,1981,1982,1983,1984,1985,1986,1987,1988,1989,1990,1991,1992,1993,1994,1995,1996,1997,1998,1999,2000,2001,2002,2003,2004,2005,2006,2007,2008,2009/Jan)

### Medicine summary (to January 2009- five ATC codes)

Reaction Count		Case Group	Death Outcomes	Sole	
Pregnancy, puerperium and perinatal conditions	Abortion missed	1	0	1	
	Abortion spontaneous	18	0	12	
	Intra-uterine death	27	3	22	
	Stillbirth	2	1	1	
	Foetal cardiac disorder	1	1	1	
	Foetal disorder	2	1	2	
	Foetal distress syndrome	4	1	2	
	Foetal growth retardation	3	1	1	
	Foetal malpresentation	1	0	1	
	Labour onset delayed	1	0	1	
	Premature labour	4	0	2	
	Premature rupture of membranes	2	0	2	
	Abnormal labour	1	0	1	
	Antepartum haemorrhage	2	0	2	
	Premature separation of placenta	2	0	2	
	Pre-eclampsia	4	0	3	
	Pregnancy induced hypertension	1	0	1	
	Ectopic pregnancy	2	0	2	
	Postmature baby	1	0	1	
	Premature baby	5	0	4	
	Birth trauma	1	0	1	
	Jaundice neonatal	3	0	2	
	Hypothermia neonatal	1	0	1	
	Neonatal disorder	26	0	19	
	Umbilical cord prolapse	1	0	1	
	Meconium stain	1	0	1	
	Polyhydramnios	2	0	2	
	Placental disorder	1	0	1	
	Postpartum haemorrhage	1	0	1	
	Unintended pregnancy	7	0	1	
	<b>Pregnancy, puerperium and perinatal conditions</b>		<b>133</b>	<b>8</b>	<b>99</b>
	Psychiatric disorders	Agitation	987	5	761
		Agitation neonatal	20	0	17
		Anxiety	546	3	431
		Nervousness	108	0	81
		Stress	9	1	6
		Tension	5	0	4
		Agoraphobia	1	1	0
		Fear	8	0	6
		Fear of death	1	0	1
		Panic attack	47	1	35
		Panic disorder	4	0	3
		Panic reaction	6	0	6
		Post-traumatic stress disorder	1	0	0
		Neurosis	54	0	42
		Obsessive thoughts	2	0	2
		Obsessive-compulsive disorder	12	0	8
		Catatonia	5	0	3
Decreased activity		1	0	1	
Restlessness		49	0	28	
Automatism		4	0	3	
Bruxism		92	0	81	
Posturing		1	0	1	
Stereotypy		1	0	0	

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count	Psychiatric disorders	Tic	Case Group	Death Outcomes	Sole
		Tic	6	0	4
		Attention deficit/hyperactivity disorder	1	0	1
		Change in sustained attention	2	0	1
		Learning disorder	2	0	2
		Reading disorder	1	0	1
		Communication disorder	3	0	3
		Expressive language disorder	1	0	0
		Mutism	1	0	0
		Verbigeration	1	0	0
		Dysphemia	1	0	0
		Pressure of speech	1	0	1
		Screaming	5	0	5
		Confusional state	659	8	361
		Disorientation	54	0	32
		Delirium	131	0	64
		Agitated depression	1	0	1
		Depression	242	6	168
		Depression suicidal	2	0	0
		Major depression	1	0	0
		Anhedonia	1	0	1
		Decreased interest	1	0	0
		Depressed mood	9	0	8
		Feeling of despair	1	0	1
		Tearfulness	10	0	8
		Depersonalisation	171	0	148
		Dissociation	9	0	7
		Delusion	46	0	32
		Delusion of grandeur	1	0	0
		Thought insertion	1	0	1
		Derealisation	2	0	1
		Hallucination	353	1	225
		Hallucination, auditory	22	0	18
		Hallucination, tactile	1	0	1
		Hallucination, visual	26	0	16
		Hallucinations, mixed	2	0	1
		Illusion	1	0	1
		Jamais vu	1	0	0
		Tachyphrenia	1	0	1
		Thinking abnormal	139	1	105
		Eating disorder	7	0	2
		Compulsive shopping	1	0	1
		Impulsive behaviour	2	0	1
		Onychophagia	1	0	1
		Pathological gambling	2	0	2
		Bipolar disorder	2	0	1
		Hypomania	12	0	8
		Mania	159	1	122
		Affect lability	69	0	57
		Inappropriate affect	4	0	2
		Anger	41	1	35
		Dysphoria	4	0	2
		Elevated mood	2	0	1
		Emotional disorder	5	0	4
		Emotional distress	5	0	4

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

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**Medicine summary (to January 2009- five ATC codes)**

Reaction Count	Psychiatric disorders	Case Group	Death Outcomes	Sole
	Euphoric mood	53	0	44
	Frustration	2	0	1
	Mood altered	9	0	7
	Mood swings	32	1	26
	Affective disorder	1	0	0
	Apathy	39	1	34
	Aggression	261	0	185
	Antisocial behaviour	1	0	1
	Disinhibition	1	0	1
	Disturbance in social behaviour	1	0	1
	Homicidal ideation	47	0	27
	Hostility	4	0	4
	Indifference	2	0	2
	Paranoia	78	4	47
	Personality change	12	1	7
	Social avoidant behaviour	2	1	1
	Violence-related symptom	10	0	6
	Personality disorder	18	0	13
	Self esteem decreased	1	0	1
	Abnormal behaviour	29	0	13
	Staring	3	0	2
	Hypervigilance	3	0	2
	Psychiatric symptom	1	0	1
	Mental disorder	6	0	2
	Mental status changes	5	0	3
	Alcohol abuse	1	0	1
	Alcohol problem	1	0	1
	Alcoholism	7	0	4
	Dependence	1	0	0
	Drug dependence	10	0	7
	Intentional drug misuse	3	0	1
	Withdrawal syndrome	574	0	529
	Delusional disorder, unspecified type	2	0	0
	Acute psychosis	3	0	2
	Psychotic disorder	113	1	75
	Schizophreniform disorder	4	0	3
	Schizophrenia	2	0	1
	Anorgasmia	112	0	106
	Premature ejaculation	4	0	3
	Disturbance in sexual arousal	2	0	2
	Libido decreased	231	0	213
	Libido increased	20	0	17
	Loss of libido	9	1	5
	Insomnia	685	2	584
	Terminal insomnia	1	0	1
	Sleep attacks	1	0	1
	Abnormal dreams	41	0	34
	Abnormal sleep-related event	13	1	2
	Nightmare	261	1	222
	Sleep talking	1	0	1
	Sleep terror	1	0	0
	Somnambulism	21	0	11
	Sleep disorder	62	0	57
	Conversion disorder	5	0	5

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count		Case Group	Death Outcomes	Sole	
Psychiatric disorders	Somatoform disorder pregnancy	1	0	1	
	Completed suicide	31	31	21	
	Intentional self-injury	17	0	13	
	Self injurious behaviour	13	1	6	
	Self-injurious ideation	11	0	10	
	Suicidal behaviour	7	1	3	
	Suicidal ideation	241	2	172	
	Suicide attempt	225	15	143	
	<b>Psychiatric disorders</b>	<b>7551</b>	<b>93</b>	<b>5670</b>	
	Renal and urinary disorders	Glomerulonephritis	1	0	0
		Nephrotic syndrome	1	0	1
		Tubulointerstitial nephritis	9	0	3
		Anuria	5	0	1
		Oliguria	9	1	5
		Renal failure	6	0	5
		Renal failure acute	45	6	8
		Renal failure chronic	2	0	0
		Renal impairment	36	1	9
		Renal tubular necrosis	2	1	2
		Urethral disorder	4	0	2
		Bladder spasm	1	0	1
		Dysuria	58	1	52
		Enuresis	3	0	2
		Micturition disorder	59	0	53
		Micturition urgency	2	0	1
		Pollakiuria	64	0	58
		Strangury	1	0	1
		Urethral pain	1	0	1
		Urinary hesitation	17	0	15
		Urinary incontinence	90	1	61
		Urinary retention	144	0	105
		Urine flow decreased	4	0	3
		Albuminuria	8	0	6
		Choluria	1	0	0
		Chromaturia	7	0	3
Glycosuria		1	0	1	
Haematuria		27	1	19	
Myoglobinuria		1	0	0	
Proteinuria		1	0	1	
Pyuria		2	0	1	
Nocturia		20	0	20	
Polyuria		19	0	17	
Renal pain		8	0	5	
Nephrolithiasis		4	0	2	
Calculus bladder	1	0	0		
<b>Renal and urinary disorders</b>	<b>664</b>	<b>12</b>	<b>464</b>		
Reproductive system and breast disorders	Breast calcifications	1	0	0	
	Breast enlargement	27	0	19	
	Breast mass	6	0	3	
	Gynaecomastia	53	0	38	
	Breast discharge	1	0	1	
	Breast engorgement	4	0	4	
	Breast pain	46	0	37	
	Breast swelling	1	0	1	

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count	Reproductive system and breast disorders	Case Group	Death Outcomes	Sole
	Breast tenderness	1	0	1
	Nipple pain	1	0	1
	Galactorrhoea	107	0	85
	Suppressed lactation	14	0	12
	Cervix disorder	1	0	0
	Epididymitis	1	0	0
	Menopausal symptoms	2	0	2
	Atrophic vulvovaginitis	2	0	2
	Dysfunctional uterine bleeding	1	0	1
	Dysmenorrhoea	2	0	2
	Menstrual disorder	25	0	21
	Menstruation irregular	4	0	2
	Metrorrhagia	27	0	20
	Premenstrual syndrome	1	0	1
	Amenorrhoea	30	0	21
	Menorrhagia	32	0	27
	Polymenorrhoea	1	0	1
	Ovarian cyst	1	0	1
	Polycystic ovaries	2	0	1
	Penile discharge	1	0	1
	Penile pain	1	0	1
	Penile size reduced	4	0	4
	Penis disorder	6	0	6
	Peyronie's disease	1	0	0
	Scrotal disorder	1	0	1
	Scrotal oedema	1	0	0
	Scrotal swelling	1	0	1
	Prostatic disorder	4	0	4
	Genital ulceration	2	0	1
	Genital discharge	2	0	1
	Genital pain	1	0	0
	Oedema genital	2	0	2
	Perineal pain	7	0	7
	Ejaculation delayed	5	0	5
	Ejaculation disorder	19	0	18
	Ejaculation failure	169	0	159
	Erectile dysfunction	134	0	118
	Priapism	14	0	10
	Dyspareunia	2	0	2
	Female sexual arousal disorder	1	0	1
	Infertility female	2	0	2
	Infertility male	1	0	1
	Sexual dysfunction	57	0	56
	Azoospermia	2	0	2
	Spermatorrhoea	2	0	2
	Testicular disorder	15	0	12
	Testicular pain	7	0	5
	Testicular retraction	1	0	0
	Uterine disorder	1	0	1
	Uterine haemorrhage	10	0	9
	Uterine pain	1	0	1
	Vaginal haemorrhage	29	0	27
	Vulval disorder	4	0	3
	Vulval ulceration	1	0	1

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count		Case Group	Death Outcomes	Sole
Reproductive system and breast disorders	Vulval erythema	1	0	1
	Vulvovaginal pain	1	0	1
	<b>Reproductive system and breast disorders</b>	<b>907</b>	<b>0</b>	<b>770</b>
Respiratory, thoracic and mediastinal disorders	Asthma	10	0	7
	Bronchospasm	40	0	34
	Chronic obstructive pulmonary disease	1	0	0
	Obstructive airways disorder	1	0	0
	Wheezing	4	0	4
	Alveolitis allergic	1	0	1
	Eosinophilic pneumonia	1	0	0
	Pneumonitis	3	0	3
	Pulmonary eosinophilia	1	0	1
	Interstitial lung disease	1	0	1
	Lung infiltration	2	1	1
	Pulmonary fibrosis	7	1	3
	Acute respiratory distress syndrome	1	0	0
	Pulmonary oedema	9	2	6
	Cyanosis neonatal	1	0	1
	Infantile apnoeic attack	5	0	3
	Neonatal asphyxia	1	0	1
	Neonatal hypoxia	1	0	1
	Neonatal respiratory depression	3	0	3
	Neonatal respiratory distress syndrome	3	0	2
	Respiratory disorder neonatal	1	0	0
	Pleural fibrosis	2	0	1
	Pleural effusion	5	0	2
	Pulmonary hypertension	6	1	1
	Pulmonary embolism	16	6	7
	Apnoea	11	0	10
	Dyspnoea	195	3	125
	Dyspnoea exertional	1	0	1
	Hyperventilation	27	0	19
	Hypopnoea	1	0	1
	Hypoventilation	3	0	2
	Respiratory arrest	2	1	2
	Respiratory depression	5	1	1
	Respiratory distress	2	0	1
	Sleep apnoea syndrome	3	0	3
	Tachypnoea	2	0	1
	Asphyxia	2	1	1
	Hypercapnia	1	0	0
	Hypoxia	9	2	3
	Respiratory alkalosis	1	0	1
	Cough	66	0	52
Haemoptysis	6	1	3	
Sputum increased	4	0	2	
Hiccups	6	0	5	
Pleuritic pain	1	0	0	
Respiratory failure	10	7	1	
Respiration abnormal	1	1	1	
Aspiration	2	0	2	
Respiratory disorder	14	0	8	
Choking	5	0	4	
Dry throat	2	0	1	

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count		Case Group	Death Outcomes	Sole	
Respiratory, thoracic and mediastinal disorders	Dysphonia	14	0	13	
	Increased upper airway secretion	1	0	1	
	Oropharyngeal pain	7	0	6	
	Rhinorrhoea	1	0	1	
	Sneezing	2	0	2	
	Snoring	2	0	2	
	Throat irritation	6	0	5	
	Throat tightness	18	0	13	
	Yawning	77	0	72	
	Laryngospasm	3	0	1	
	Stridor	2	0	1	
	Nasal congestion	2	0	1	
	Epistaxis	46	0	34	
	Nasal dryness	1	0	1	
	Sinus congestion	3	0	3	
	Oropharyngeal swelling	2	0	1	
	Pharyngeal oedema	8	0	8	
	<b>Respiratory, thoracic and mediastinal disorders</b>		<b>703</b>	<b>28</b>	<b>498</b>
	Skin and subcutaneous tissue disorders	Angioedema	62	0	41
		Periorbital oedema	42	0	35
Urticaria		258	0	211	
Urticaria papular		1	0	1	
Mechanical urticaria		3	0	3	
Lichenoid keratosis		9	0	6	
Skin hypertrophy		4	0	2	
Skin atrophy		1	0	0	
Leukoplakia		1	0	0	
Blister		4	0	2	
Dermatitis bullous		34	0	26	
Erythema multiforme		25	0	15	
Pemphigoid		1	0	0	
Stevens-Johnson syndrome		5	0	1	
Toxic epidermal necrolysis		2	1	0	
Cutaneous lupus erythematosus		1	0	1	
Dry skin		16	0	15	
Hypoaesthesia facial		2	0	2	
Skin burning sensation		5	0	4	
Skin discolouration		15	0	12	
Skin disorder		7	0	4	
Skin necrosis		1	0	1	
Skin odour abnormal		5	0	4	
Skin reaction		3	0	2	
Swelling face		14	0	10	
Yellow skin		1	0	1	
Dermatitis		9	0	7	
Dermatitis allergic		1	0	1	
Eczema		14	0	11	
Neurodermatitis		1	0	1	
Stasis dermatitis		1	0	1	
Drug eruption		3	0	2	
Erythema	10	0	6		
Rash erythematous	132	0	96		
Dermatitis exfoliative	11	0	6		
Exfoliative rash	2	0	2		

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

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**Medicine summary (to January 2009- five ATC codes)**

Reaction Count	Outcome Description	Case Group	Death Outcomes	Sole
	Skin and subcutaneous tissue disorders			
	Skin exfoliation	30	0	26
	Lichen sclerosus	1	0	0
	Lichenification	1	0	0
	Rash papular	12	0	9
	Photosensitivity allergic reaction	2	0	0
	Photosensitivity reaction	98	0	69
	Pruritus	513	1	392
	Pruritus generalised	3	0	2
	Rash pruritic	14	0	11
	Dermatitis psoriasiform	7	0	6
	Psoriasis	16	0	12
	Pustular psoriasis	1	0	1
	Acute generalised exanthematous pustulosis	1	0	0
	Rash follicular	3	0	2
	Fixed eruption	6	0	4
	Rash	518	3	381
	Rash generalised	2	0	1
	Rash macular	5	0	1
	Rash maculo-papular	225	0	167
	Rash morbilliform	16	0	8
	Rash neonatal	1	0	1
	Rash vesicular	14	0	11
	Systemic lupus erythematosus rash	4	0	2
	Pityriasis	1	0	1
	Chloasma	6	0	4
	Skin hyperpigmentation	2	0	1
	Skin depigmentation	1	0	1
	Vitiligo	2	0	1
	Lipodystrophy acquired	3	0	0
	Erythema nodosum	12	0	11
	Skin nodule	1	0	0
	Skin ulcer	2	0	2
	Acne	48	0	39
	Alopecia	128	1	96
	Anhidrosis	2	0	2
	Cold sweat	27	0	19
	Hyperhidrosis	747	2	560
	Hypohidrosis	1	0	1
	Night sweats	11	0	7
	Hirsutism	5	0	3
	Hypertrichosis	2	0	1
	Nail disorder	12	0	10
	Hair colour changes	4	0	1
	Hair texture abnormal	11	0	9
	Piloerection	2	0	2
	Rosacea	2	0	1
	Seborrhoea	2	0	2
	Ecchymosis	5	0	5
	Henoch-Schonlein purpura	2	0	2
	Increased tendency to bruise	3	0	2
	Petechiae	4	0	3
	Purpura	211	3	158
	Haemorrhage subcutaneous	1	0	0
	Leukocytoclastic vasculitis	2	0	2

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

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### Medicine summary (to January 2009- five ATC codes)

Reaction Count		Case Group	Death Outcomes	Sole	
	Skin and subcutaneous tissue disorders	<b>Skin and subcutaneous tissue disorders</b>	<b>3461</b>	<b>11</b>	<b>2584</b>
	Social circumstances	Physical assault	5	0	2
		Sexual abuse	2	0	2
		Alcohol use	2	0	1
		Activities of daily living impaired	1	0	1
		Impaired work ability	1	0	1
		Walking disability	1	0	0
		<b>Social circumstances</b>	<b>12</b>	<b>0</b>	<b>7</b>
	Surgical and medical procedures	Colectomy	1	0	1
		Abortion induced	2	1	2
		Drug therapy changed	42	0	40
		Therapy regimen changed	66	0	41
		<b>Surgical and medical procedures</b>	<b>111</b>	<b>1</b>	<b>84</b>
	Vascular disorders	Aneurysm	2	2	1
		Aortic stenosis	1	0	1
		Ischaemia	1	0	1
		Vasospasm	1	0	1
		Intermittent claudication	1	0	1
		Peripheral ischaemia	17	0	9
		Poor peripheral circulation	1	0	0
		Raynaud's phenomenon	2	0	2
		Peripheral coldness	2	0	2
		Blood pressure fluctuation	2	0	1
		Circulatory collapse	36	2	13
		Shock	2	0	1
		Hypoperfusion	1	1	1
		Hypotension	169	6	81
		Orthostatic hypotension	178	0	107
		Thrombosis	5	1	4
		Embolism venous	1	0	0
		Deep vein thrombosis	11	3	5
		Thrombophlebitis	2	0	0
		Lymphoedema	1	0	1
		Angiopathy	1	0	0
		Vasodilatation	6	1	5
		Vein disorder	1	0	1
		Vein pain	1	0	1
		Flushing	159	0	119
		Hot flush	72	0	57
		Pallor	22	1	14
		Haematoma	9	0	6
		Haemorrhage	16	1	9
		Hypertensive crisis	2	0	2
		Malignant hypertension	1	0	1
		Hypertension	214	1	136
		Maternal hypertension affecting foetus	1	0	0
		Arteritis	2	0	0
		Phlebitis	2	0	2
		Vasculitis	18	0	13
		<b>Vascular disorders</b>	<b>963</b>	<b>19</b>	<b>598</b>
	<b>Reaction</b>		<b>36804</b>	<b>587</b>	<b>26397</b>

Rows are suppressed based on zeros and empty cells for Case Group

Outcome Description

(Causality possible,Causality probable,Causality certain)

Suspect Type

Suspect Code

Case Group

GM

(Other antidepressants, Selective serotonin reuptake inhibitors, Non-selective monoamine reuptake inhibitors, Monoamine oxidase A inhibitors, Monoamine oxidase inhibitors, non-selective)

(1971,1972,1973,1974,1975,1976,1977,1978,1979,1980,1981,1982,1983,1984,1985,1986,1987,1988,1989,1990,1991,1992,1993,1994,1995,1996,1997,1998,1999,2000,2001,2002,2003,2004,2005,2006,2007,2008,2009/Jan)