

## **Medicine summary - venlafaxine (to end January 2009)**

		Case Group	Death Outcomes	Sole
Case Count		<b>1485</b>	<b>28</b>	<b>1052</b>
Reaction Count	Blood and lymphatic system disorders	Anaemia Bone marrow failure Pancytopenia Coagulopathy Coombs positive haemolytic anaemia Thrombocytopenia Lymphadenopathy Spleen disorder Eosinophilia Leukocytosis Neutrophilia Leukopenia Lymphopenia Agranulocytosis Neutropenia	5 1 1 3 1 4 1 1 2 4 1 7 3 3 12	1 0 0 1 0 1 0 0 0 0 0 1 0 0 4
		<b>Blood and lymphatic system disorders</b>	<b>49</b>	<b>3</b>
	Cardiac disorders	Bundle branch block right Arrhythmia Bradycardia Extrasystoles Tachycardia Atrial fibrillation Atrial flutter Atrial tachycardia Sinus tachycardia Supraventricular tachycardia Cardiac arrest Torsade de pointes Ventricular fibrillation Ventricular tachycardia Cyanosis Palpitations Mitral valve prolapse Angina pectoris Myocardial infarction Cardiac failure Cardiomyopathy Cardiomegaly Left atrial dilatation Ventricular hypokinesia Myocarditis	1 1 3 3 36 3 1 1 2 3 6 1 2 2 1 20 1 1 2 1 5 1 1 1 1 1	0 0 0 0 0 0 0 0 0 0 3 0

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Reaction Count			Case Group	Death Outcomes	Sole
	Cardiac disorders	<b>Cardiac disorders</b>	<b>100</b>	<b>5</b>	<b>65</b>
	Congenital, familial and genetic disorders	Heart disease congenital	3	1	2
		Transposition of the great vessels	1	0	1
		Trisomy 18	1	0	1
		Trisomy 21	1	0	0
		Cytogenetic abnormality	1	0	1
		Hemihypertrophy	2	0	2
		Multiple congenital abnormalities	3	0	1
		Hernia congenital	1	0	0
		Cleft palate	1	0	0
		Congenital hand malformation	1	0	1
		Limb malformation	1	0	0
		Polydactyly	1	0	1
		Talipes	1	0	1
		Cerebral palsy	1	0	0
		Kidney malformation	1	0	0
		Pulmonary malformation	1	0	1
		<b>Congenital, familial and genetic disorders</b>	<b>21</b>	<b>1</b>	<b>12</b>
	Ear and labyrinth disorders	Ear pain	2	0	2
		Deafness	1	0	1
		Hearing impaired	2	0	2
		Inner ear disorder	1	0	1
		Motion sickness	1	0	1
		Tinnitus	15	0	13
		Vertigo	19	0	15
		Eustachian tube obstruction	1	0	1
		<b>Ear and labyrinth disorders</b>	<b>42</b>	<b>0</b>	<b>36</b>
	Endocrine disorders	Inappropriate antidiuretic hormone secretion	20	0	14
		Hypothyroidism	1	0	1
		<b>Endocrine disorders</b>	<b>21</b>	<b>0</b>	<b>15</b>
	Eye disorders	Cataract	1	0	1
		Xerophthalmia	1	0	1
		Lacrimal disorder	1	0	1
		Eye pain	5	0	4
		Ocular discomfort	1	0	1
		Angle closure glaucoma	1	0	1
		Glaucoma	5	0	2
		Conjunctivitis	1	0	0
		Ocular hyperaemia	1	0	1
		Blepharospasm	1	0	1
		Oculogyric crisis	3	0	2
		Miosis	1	0	1

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		Case Group	Death Outcomes	Sole
Reaction Count	Eye disorders	Mydriasis	26	0    18
		Eye rolling	3	0    1
		Eyelid sensory disorder	1	0    1
		Photophobia	5	0    5
		Myodesopsia	1	0    1
		Vitreous detachment	1	0    1
		Blindness	1	0    1
		Accommodation disorder	1	0    1
		Xanthopsia	1	0    1
		Diplopia	5	0    4
		Photopsia	1	0    1
		Vision blurred	14	0    11
		Visual impairment	30	0    26
		Scotoma	1	0    0
		<b>Eye disorders</b>	<b>113</b>	<b>0    88</b>
	Gastrointestinal disorders	Rectal tenesmus	1	0    1
		Dental caries	1	0    0
		Tooth disorder	1	0    0
		Tooth discolouration	1	0    1
		Gingivitis	1	0    1
		Pancreatitis	4	0    3
		Pancreatitis acute	1	0    1
		Gastric disorder	1	0    1
		Gastrointestinal disorder	1	0    1
		Rectal haemorrhage	1	0    1
		Haematemesis	4	0    1
		Melaena	1	0    0
		Colitis ulcerative	1	0    1
		Gastritis	1	0    1
		Enteritis	2	0    1
		Oesophagitis	1	0    1
		Diarrhoea	38	1    32
		Constipation	18	0    15
		Frequent bowel movements	1	0    1
		Irritable bowel syndrome	1	0    1
		Ileus paralytic	1	0    1
		Dyspepsia	12	0    10
		Abnormal faeces	2	0    2
		Flatulence	2	0    2
		Abdominal pain	14	0    12
		Abdominal pain upper	4	0    4
		Abdominal discomfort	4	0    4

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		Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Dysphagia	8	0 7
		Faecal incontinence	1	0 1
		Nausea	159	0 132
		Retching	2	0 2
		Vomiting	93	1 73
		Vomiting in pregnancy	1	0 1
		Intestinal obstruction	1	0 0
		Gastric ulcer	1	0 0
		Chapped lips	1	0 1
		Cheilitis	1	0 1
		Aphthous stomatitis	1	0 1
		Mouth ulceration	1	0 1
		Stomatitis	4	0 4
		Aptyalism	1	0 1
		Dry mouth	20	0 18
		Salivary hypersecretion	4	0 4
		Glossitis	4	0 1
		Tongue disorder	2	0 2
		Tongue ulceration	1	0 1
		Tongue discolouration	1	0 1
		Tongue oedema	5	0 5
		<b>Gastrointestinal disorders</b>	<b>432</b>	<b>2 356</b>
General disorders and administration site conditions	General disorders and administration site conditions	Hyperthermia	1	0 1
		Hyperthermia malignant	1	0 1
		Pyrexia	24	1 7
		Death	1	1 0
		Death neonatal	1	1 1
		Sudden death	6	6 1
		Asthenia	22	0 17
		Fatigue	55	0 40
		Malaise	29	1 22
		Abasia	1	0 1
		Gait disturbance	11	0 7
		Condition aggravated	5	0 4
		Energy increased	1	0 1
		Influenza like illness	8	0 7
		Irritability	11	0 9
		Multi-organ failure	1	1 0
		Face oedema	5	0 4
		Gravitational oedema	3	0 2
		Oedema	6	0 1
		Oedema peripheral	6	0 3

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			<b>Case Group</b>	<b>Death Outcomes</b>	<b>Sole</b>
Reaction Count	General disorders and administration site conditions	Chest pain	12	0	10
		Pain	11	0	9
		Chest discomfort	2	0	2
		Chills	26	0	17
		Feeling abnormal	13	0	13
		Feeling cold	1	0	0
		Feeling hot	3	0	2
		Feeling jittery	4	0	3
		Feeling of body temperature change	4	0	3
		Hunger	1	0	1
		Thirst	4	0	4
		Drug interaction	9	0	0
		Drug effect decreased	6	0	5
		Drug ineffective	35	2	28
		Therapeutic response decreased	2	0	1
		Drug withdrawal syndrome	40	0	37
		Drug withdrawal syndrome neonatal	12	0	9
		Rebound effect	1	0	1
		<b>General disorders and administration site conditions</b>	<b>384</b>	<b>13</b>	<b>274</b>
	Hepatobiliary disorders	Cholecystitis	1	0	0
		Jaundice	3	0	2
		Hepatic function abnormal	16	1	8
		Hepatic failure	5	1	2
		Hepatitis	5	1	4
		Hepatitis chronic active	1	0	1
		Hepatitis fulminant	1	0	0
		Hepatocellular injury	1	0	0
		<b>Hepatobiliary disorders</b>	<b>33</b>	<b>3</b>	<b>17</b>
	Immune system disorders	Hypersensitivity	3	0	3
		Anaphylactic shock	1	0	1
		Anaphylactoid reaction	3	0	3
		<b>Immune system disorders</b>	<b>7</b>	<b>0</b>	<b>7</b>
	Infections and infestations	Bacterial infection	1	0	0
		Cellulitis	1	0	1
		Candidiasis	1	0	0
		Genital candidiasis	1	0	1
		Gastroenteritis	1	0	1
		Infection	1	0	1
		Pneumonia	3	0	2
		Sepsis	1	1	0
		Rash pustular	1	0	0

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		Case Group	Death Outcomes	Sole
Reaction Count	Infections and infestations	Nasopharyngitis	1	0 1
		Pharyngitis	3	0 3
		Sinusitis	1	0 1
		Gastritis viral	1	0 1
		Gastroenteritis viral	1	0 1
		<b>Infections and infestations</b>	<b>18</b>	<b>1 13</b>
	Injury, poisoning and procedural complications	Drug toxicity	1	1 1
		Poisoning	1	0 1
		Drug exposure before pregnancy	1	0 1
		Drug exposure during pregnancy	23	1 16
		Maternal drugs affecting foetus	1	1 1
		Subdural haemorrhage	1	0 1
		Fall	7	0 0
		Uterine injury	1	0 1
		Head injury	2	0 0
		Contusion	3	0 1
		Chillblains	1	0 0
		Heat stroke	2	1 1
		Inappropriate schedule of drug administration	1	0 1
		Medication error	3	0 0
		Accidental overdose	1	0 1
		Intentional overdose	7	1 6
		Overdose	10	0 5
		Post procedural haemorrhage	1	0 1
		<b>Injury, poisoning and procedural complications</b>	<b>67</b>	<b>5 38</b>
	Investigations	Cardiac murmur	1	0 1
		Electrocardiogram QT prolonged	8	1 4
		Electrocardiogram abnormal	2	0 1
		Heart rate increased	3	0 3
		Blood pressure decreased	2	0 2
		Blood pressure increased	10	0 10
		Blood prolactin increased	2	0 1
		Blood testosterone decreased	1	0 0
		Blood testosterone increased	1	0 0
		Blood creatine phosphokinase increased	8	1 3
		Blood alkaline phosphatase increased	2	0 0
		Blood lactate dehydrogenase increased	1	0 0
		Bleeding time prolonged	1	0 0
		International normalised ratio decreased	1	0 0
		International normalised ratio increased	1	0 0
		Prothrombin level decreased	1	0 1

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Reaction Count			Case Group	Death Outcomes	Sole
	Investigations	Prothrombin level increased	2	0	0
		Red blood cell sedimentation rate increased	1	0	0
		White blood cell count increased	1	0	0
		Alanine aminotransferase increased	2	0	0
		Aspartate aminotransferase increased	1	0	0
		Blood bilirubin increased	1	0	0
		Gamma-glutamyltransferase increased	2	0	0
		Hepatic enzyme increased	1	0	0
		Liver function test abnormal	13	0	8
		Antinuclear antibody positive	2	0	0
		Blood cholesterol increased	4	0	1
		Total cholesterol/HDL ratio decreased	1	0	0
		Blood triglycerides increased	3	0	1
		Blood glucose decreased	1	0	1
		Blood glucose increased	1	0	1
		Intraocular pressure increased	1	0	1
		Body temperature decreased	1	0	1
		Weight decreased	12	0	10
		Weight increased	19	0	15
		C-reactive protein increased	1	0	0
		Semen analysis abnormal	1	0	1
		Antidepressant drug level above therapeutic	1	0	1
		Antipsychotic drug level increased	1	0	0
		Drug level above therapeutic	1	0	0
		Drug level decreased	2	0	0
		Drug level increased	3	0	0
		Blood phosphorus decreased	1	0	0
		<b>Investigations</b>	<b>125</b>	<b>2</b>	<b>67</b>
	Metabolism and nutrition disorders	Acidosis	2	1	0
		Decreased appetite	33	1	28
		Food craving	1	0	1
		Increased appetite	3	0	2
		Feeding disorder neonatal	1	0	1
		Weight loss poor	1	0	1
		Hypercalcaemia	1	0	0
		Hypocalcaemia	2	1	1
		Tetany	2	0	2
		Hyperchloraemia	1	1	0
		Hypochloraemia	2	0	0
		Polydipsia	1	0	1
		Hyperkalaemia	2	0	0
		Hypokalaemia	9	1	2

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Reaction Count			Case Group	Death Outcomes	Sole	
	Metabolism and nutrition disorders	Hypernatraemia	2	0	1	
		Hyponatraemia	92	1	56	
		Dehydration	6	0	4	
		Fluid retention	3	0	3	
		Alcohol intolerance	1	0	1	
		Diabetes mellitus	1	0	1	
		Gestational diabetes	1	0	1	
		Hyperglycaemia	1	0	1	
		Hypoglycaemia	6	0	2	
		<b>Metabolism and nutrition disorders</b>	<b>174</b>	<b>6</b>	<b>109</b>	
	Musculoskeletal and connective tissue disorders	Jaw disorder	1	0	1	
		Systemic lupus erythematosus	1	0	1	
		Arthritis	6	0	3	
		Arthralgia	11	0	8	
		Joint stiffness	1	0	1	
		Osteoarthritis	2	0	1	
		Myalgia	29	0	23	
		Muscle spasms	9	0	5	
		Muscle tightness	3	0	3	
		Muscle twitching	19	0	13	
		Hypertonia neonatal	1	0	1	
		Muscle rigidity	6	0	2	
		Torticollis	1	0	0	
		Trismus	5	0	4	
		Muscular weakness	2	0	1	
		Rhabdomyolysis	4	1	1	
		Mobility decreased	3	0	0	
		Musculoskeletal stiffness	4	0	3	
		Back pain	2	0	2	
		Neck pain	1	0	1	
		Pain in extremity	2	0	2	
		<b>Musculoskeletal and connective tissue disorders</b>	<b>113</b>	<b>1</b>	<b>76</b>	
	Nervous system disorders	Cerebrovascular accident	4	0	4	
		Haemorrhagic stroke	2	0	2	
		Cerebrovascular disorder	3	1	2	
		Facial palsy	1	0	1	
		Encephalopathy	5	0	4	
		Drug withdrawal headache	1	0	1	
		Headache	106	0	83	
		Migraine	6	0	3	
		Migraine with aura	1	0	1	

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Reaction Count		Case Group	Death Outcomes	Sole
	Nervous system disorders	Benign intracranial hypertension	1	0 1
		Brain oedema	1	0 0
		Amnesia	18	0 13
		Memory impairment	5	0 2
		Cognitive disorder	2	0 2
		Disturbance in attention	15	0 11
		Mental impairment	3	0 3
		Choreoathetosis	4	0 3
		Akathisia	27	2 18
		Bradykinesia	1	0 1
		Dyskinesia	15	0 8
		Extrapyramidal disorder	7	0 4
		Hyperkinesia	5	0 3
		Hypokinesia	2	0 0
		Movement disorder	2	0 1
		Psychomotor hyperactivity	4	0 3
		Tardive dyskinesia	8	0 4
		Dystonia	19	0 11
		Opisthotonus	2	0 1
		Paresis	1	0 1
		Cogwheel rigidity	2	0 1
		Masked facies	1	0 0
		Parkinsonism	6	0 3
		Tremor	89	0 54
		Hyperreflexia	9	0 4
		Hyporeflexia	1	0 1
		Reflexes abnormal	1	0 0
		Ataxia	25	0 22
		Balance disorder	7	0 2
		Coordination abnormal	10	0 7
		Dysstasia	3	0 3
		Nystagmus	4	0 2
		Coma	5	0 2
		Aphasia	1	0 0
		Consciousness fluctuating	3	0 1
		Depressed level of consciousness	5	0 1
		Lethargy	6	0 3
		Loss of consciousness	6	1 4
		Sedation	2	0 1
		Somnolence	41	0 28
		Stupor	1	0 1
		Syncope	28	0 18

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Case Group	Death Outcomes	Sole
Reaction Count	Nervous system disorders	
	Motor dysfunction	1      0      1
	Clonus	2      0      1
	Dizziness	117     0      95
	Head discomfort	2      0      2
	Myoclonus	3      0      0
	Neurological symptom	1      0      1
	Presyncope	2      0      2
	Tongue biting	1      0      0
	Crying	4      0      4
	Burning sensation	2      0      2
	Hyperaesthesia	5      0      4
	Paraesthesia	52     0      46
	Dysgeusia	6      0      6
	Hypoesthesia	13     0      12
	Restless legs syndrome	1      0      1
	Sensory disturbance	5      0      4
	Dysarthria	8      0      7
	Incoherent	1      0      0
	Speech disorder	4      0      1
	Tunnel vision	1      0      1
	Visual field defect	2      0      2
	Horner's syndrome	1      0      1
	Hypertonia	23     0      10
	Neuroleptic malignant syndrome	11     1      3
	Serotonin syndrome	50     0      15
	Muscle contractions involuntary	1      0      0
	Myasthenia gravis	1      0      0
	Neuropathy peripheral	2      0      2
	Petit mal epilepsy	1      0      1
	Convulsion neonatal	2      0      0
	Grand mal convulsion	12     0      5
	Convulsion	58     0      32
	Convulsive threshold lowered	1      0      1
	Drug withdrawal convulsions	1      0      0
	Epilepsy	5      0      4
	Status epilepticus	2      0      2
	Tonic convulsion	1      0      1
	Circadian rhythm sleep disorder	1      0      0
	Hypersomnia	2      0      1
	Narcolepsy	1      0      0
	Poor quality sleep	2      0      2
	<b>Nervous system disorders</b>	<b>938     5      621</b>

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		Case Group	Death Outcomes	Sole
Reaction Count	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	5	0    4
		Intra-uterine death	1	0    1
		Foetal distress syndrome	1	1    1
		Premature labour	1	0    1
		Abnormal labour	1	0    1
		Premature separation of placenta	1	0    1
		Pre-eclampsia	2	0    2
		Pregnancy induced hypertension	1	0    1
		Ectopic pregnancy	1	0    1
		Premature baby	3	0    3
		Birth trauma	1	0    1
		Jaundice neonatal	1	0    0
		Neonatal disorder	4	0    3
		Polyhydramnios	1	0    1
		Placental disorder	1	0    1
		Unintended pregnancy	1	0    0
		<b>Pregnancy, puerperium and perinatal conditions</b>	<b>26</b>	<b>1    22</b>
	Psychiatric disorders	Agitation	80	0    60
		Agitation neonatal	2	0    2
		Anxiety	66	0    47
		Nervousness	10	0    9
		Stress	2	0    1
		Tension	1	0    1
		Fear	3	0    3
		Panic attack	9	0    7
		Panic disorder	1	0    1
		Neurosis	1	0    1
		Obsessive-compulsive disorder	2	0    2
		Catatonia	1	0    0
		Decreased activity	1	0    1
		Restlessness	7	0    4
		Automatism	2	0    2
		Bruxism	10	0    9
		Posturing	1	0    1
		Stereotypy	1	0    0
		Tic	1	0    1
		Learning disorder	1	0    1
		Pressure of speech	1	0    1
		Confusional state	60	0    36
		Disorientation	15	0    10
		Delirium	19	0    12

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Reaction Count	Psychiatric disorders	Case Group	Death Outcomes	Sole
	Depression	<b>35</b>	0	<b>26</b>
	Depression suicidal	1	0	0
	Major depression	1	0	0
	Anhedonia	1	0	1
	Decreased interest	1	0	0
	Depressed mood	3	0	2
	Tearfulness	3	0	2
	Depersonalisation	<b>15</b>	0	<b>13</b>
	Dissociation	1	0	0
	Delusion	5	0	5
	Derealisation	1	0	0
	Hallucination	<b>34</b>	0	<b>17</b>
	Hallucination, auditory	3	0	2
	Hallucination, visual	1	0	1
	Hallucinations, mixed	1	0	1
	Thinking abnormal	<b>18</b>	0	<b>13</b>
	Eating disorder	4	0	1
	Hypomania	3	0	1
	Mania	<b>15</b>	0	<b>11</b>
	Affect lability	8	0	6
	Inappropriate affect	1	0	0
	Anger	<b>10</b>	0	<b>8</b>
	Dysphoria	2	0	1
	Elevated mood	1	0	0
	Emotional disorder	3	0	3
	Euphoric mood	5	0	4
	Mood altered	2	0	2
	Mood swings	7	0	7
	Affective disorder	1	0	0
	Apathy	6	0	6
	Aggression	<b>39</b>	0	<b>27</b>
	Disinhibition	1	0	1
	Disturbance in social behaviour	1	0	1
	Homicidal ideation	<b>20</b>	0	<b>10</b>
	Hostility	3	0	3
	Indifference	1	0	1
	Paranoia	<b>12</b>	0	<b>10</b>
	Personality change	2	0	1
	Violence-related symptom	3	0	2
	Self esteem decreased	1	0	1
	Abnormal behaviour	7	0	6
	Staring	1	0	1

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		Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Hypervigilance	1	0
		Psychiatric symptom	1	0
		Mental status changes	2	0
		Alcohol abuse	1	0
		Alcohol problem	1	0
		Alcoholism	2	0
		Dependence	1	0
		Drug dependence	2	0
		Intentional drug misuse	1	0
		Withdrawal syndrome	105	0
		Psychotic disorder	13	0
		Schizophreniform disorder	1	0
		Schizophrenia	1	0
		Anorgasmia	5	0
		Premature ejaculation	1	0
		Libido decreased	11	0
		Loss of libido	4	0
		Insomnia	54	0
		Abnormal dreams	10	0
		Abnormal sleep-related event	5	0
		Nightmare	30	0
		Somnambulism	4	0
		Sleep disorder	2	0
		Conversion disorder	2	0
		Completed suicide	12	12
		Intentional self-injury	3	0
		Self injurious behaviour	1	0
		Self-injurious ideation	3	0
		Suicidal behaviour	1	0
		Suicidal ideation	82	1
		Suicide attempt	56	2
		<b>Psychiatric disorders</b>	<b>998</b>	<b>15</b>
	Renal and urinary disorders	Oliguria	1	0
		Renal failure acute	3	0
		Renal impairment	4	0
		Urethral disorder	1	0
		Dysuria	3	0
		Enuresis	1	0
		Micturition disorder	8	0
		Micturition urgency	1	0
		Pollakiuria	4	0
		Urinary hesitation	2	0

## **Medicine summary - venlafaxine (to end January 2009)**

		Case Group	Death Outcomes	Sole
Reaction Count	Renal and urinary disorders Reproductive system and breast disorders Respiratory, thoracic and mediastinal disorders	Urinary incontinence Urinary retention Haematuria Nocturia Polyuria Nephrolithiasis <b>Renal and urinary disorders</b>	<b>9</b> <b>10</b> <b>2</b> <b>1</b> <b>1</b> <b>2</b> <b>53</b>	<b>0</b> <b>0</b> <b>0</b> <b>0</b> <b>0</b> <b>0</b> <b>0</b>
		Breast enlargement	1	0 0
		Gynaecomastia	7	0 5
		Breast pain	2	0 1
		Breast swelling	1	0 1
		Galactorrhoea	7	0 5
		Menstrual disorder	1	0 1
		Menstruation irregular	2	0 1
		Metrorrhagia	3	0 1
		Amenorrhoea	7	0 3
		Menorrhagia	4	0 3
		Polymenorrhoea	1	0 1
		Polycystic ovaries	2	0 1
		Penile size reduced	1	0 1
		Prostatic disorder	2	0 2
		Oedema genital	1	0 1
		Ejaculation delayed	1	0 1
		Ejaculation disorder	1	0 0
		Erectile dysfunction	4	0 2
		Priapism	1	0 1
		Sexual dysfunction	5	0 5
		Spermatorrhoea	1	0 1
		Testicular disorder	1	0 1
		Testicular pain	1	0 0
		Uterine haemorrhage	1	0 0
		Vaginal haemorrhage	1	0 1
		<b>Reproductive system and breast disorders</b>	<b>59</b>	<b>0 39</b>
		Asthma	1	0 1
		Bronchospasm	2	0 2
		Pneumonitis	1	0 1
		Pulmonary eosinophilia	1	0 1
		Pulmonary oedema	3	1 1
		Infantile apnoeic attack	1	0 1
		Pulmonary hypertension	1	0 0
		Pulmonary embolism	2	1 1
		Apnoea	3	0 2

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		Case Group	Death Outcomes	Sole
Reaction Count	Respiratory, thoracic and mediastinal disorders	Dyspnoea	19	1    12
		Hyperventilation	5	0    3
		Hypopnoea	1	0    1
		Sleep apnoea syndrome	2	0    2
		Tachypnoea	1	0    1
		Hypoxia	1	0    0
		Respiratory alkalosis	1	0    1
		Cough	3	0    2
		Hiccups	1	0    1
		Respiration abnormal	1	1    1
		Respiratory disorder	1	0    0
		Increased upper airway secretion	1	0    1
		Sneezing	1	0    1
		Throat tightness	2	0    0
		Yawning	10	0    9
		Epistaxis	3	0    2
		Oropharyngeal swelling	1	0    0
		Pharyngeal oedema	1	0    1
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>70</b>	<b>4    48</b>
	Skin and subcutaneous tissue disorders	Angioedema	10	0    8
		Urticaria	20	0    16
		Leukoplakia	1	0    0
		Dermatitis bullous	1	0    0
		Erythema multiforme	2	0    1
		Stevens-Johnson syndrome	1	0    0
		Cutaneous lupus erythematosus	1	0    1
		Dry skin	1	0    1
		Skin burning sensation	1	0    1
		Skin discolouration	1	0    0
		Skin odour abnormal	1	0    0
		Eczema	1	0    0
		Erythema	2	0    2
		Rash erythematous	7	0    5
		Dermatitis exfoliative	1	0    0
		Skin exfoliation	3	0    3
		Rash papular	2	0    2
		Photosensitivity reaction	4	0    1
		Pruritus	39	0    28
		Pruritus generalised	1	0    0
		Rash pruritic	2	0    1
		Dermatitis psoriasiform	1	0    1

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			Case Group	Death Outcomes	Sole
Reaction Count	Skin and subcutaneous tissue disorders	Psoriasis	1	0	0
		Rash follicular	1	0	1
		Rash	25	0	19
		Rash maculo-papular	13	0	11
		Systemic lupus erythematosus rash	1	0	1
		Acne	3	0	3
		Alopecia	6	0	4
		Cold sweat	4	0	3
		Hyperhidrosis	96	0	72
		Hypohidrosis	1	0	1
		Night sweats	1	0	0
		Hirsutism	1	0	0
		Piloerection	2	0	2
		Ecchymosis	1	0	1
		Purpura	16	0	14
		Haemorrhage subcutaneous	1	0	0
		Leukocytoclastic vasculitis	1	0	1
		<b>Skin and subcutaneous tissue disorders</b>	<b>277</b>	<b>0</b>	<b>204</b>
	Social circumstances	Sexual abuse	1	0	1
		Activities of daily living impaired	1	0	1
		Impaired work ability	1	0	1
		<b>Social circumstances</b>	<b>3</b>	<b>0</b>	<b>3</b>
	Surgical and medical procedures	Colectomy	1	0	1
		Therapy regimen changed	16	0	11
		<b>Surgical and medical procedures</b>	<b>17</b>	<b>0</b>	<b>12</b>
	Vascular disorders	Aneurysm	1	1	1
		Vasospasm	1	0	1
		Peripheral ischaemia	2	0	1
		Poor peripheral circulation	1	0	0
		Blood pressure fluctuation	1	0	1
		Circulatory collapse	7	2	2
		Hypoperfusion	1	1	1
		Hypotension	17	1	7
		Orthostatic hypotension	15	0	10
		Thrombosis	1	0	1
		Deep vein thrombosis	2	1	1
		Thrombophlebitis	1	0	0
		Vasodilatation	1	0	1
		Flushing	20	0	15
		Hot flush	5	0	4
		Pallor	4	0	2
		Haemorrhage	1	0	1

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			Case Group	Death Outcomes	Sole
Reaction Count	Vascular disorders	Hypertension	47	0	32
		Maternal hypertension affecting foetus	1	0	0
		Vasculitis	1	0	1
		<b>Vascular disorders</b>	<b>130</b>	<b>6</b>	<b>82</b>
	<b>Reaction</b>		<b>4270</b>	<b>73</b>	<b>2992</b>