



THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

VENLAFAXINE HYDROCHLORIDE		Layer 1 of 1		
		ALL REPORT DATES		
		Causality Unclear Excluded		
		Total	Death Outcome	Sole Suspected
- Cases Including Medicine		1305	27	913
- Occurrences of Medicine		1325	28	913
- Reactions Related to Medicine		3649	68	2499
Blood and lymphatic system disorders	Anaemia	4	1	3
	Bone marrow failure	1	0	1
	Pancytopenia	1	0	1
	Coagulopathy	3	1	1
	Coombs positive haemolytic anaemia	1	0	1
	Thrombocytopenia	4	1	1
	Lymphadenopathy	1	0	0
	Spleen disorder	1	0	1
	Eosinophilia	2	0	1
	Leukocytosis	4	0	1
	Neutrophilia	1	0	0
	Leukopenia	7	0	1
	Lymphopenia	3	0	1
	Agranulocytosis	3	0	1
	Neutropenia	12	0	4
Cardiac disorders	Arrhythmia	1	0	1
	Bradycardia	1	0	1
	Extrasystoles	3	0	3
	Tachycardia	31	0	15
	Atrial fibrillation	3	0	3
	Atrial flutter	1	0	1
	Atrial tachycardia	1	0	1
	Supraventricular tachycardia	3	0	2
	Cardiac arrest	4	3	0
	Torsade de pointes	1	0	0
	Ventricular fibrillation	1	0	1
	Ventricular tachycardia	2	0	1
	Cyanosis	1	0	1

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VENLAFAXINE HYDROCHLORIDE		Layer 1 of 1		
Cardiac disorders	Palpitations	13	0	12
	Mitral valve prolapse	1	0	0
	Angina pectoris	1	0	1
	Myocardial infarction	2	0	2
	Cardiac failure	1	0	1
	Cardiomyopathy	5	1	4
	Cardiomegaly	1	0	1
	Myocarditis	1	1	0
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
	Chromosome abnormality	1	0	1
	Hemihypertrophy	2	0	2
	Multiple congenital abnormalities	3	0	1
	Cleft palate	1	0	0
	Congenital hand malformation	1	0	1
	Limb malformation	1	0	0
	Polydactyly	1	0	1
	Talipes	1	0	1
	Kidney malformation	1	0	0
Ear and labyrinth disorders	Ear pain	3	0	3
	Deafness	1	0	1
	Hearing impaired	1	0	1
	Inner ear disorder	1	0	1
	Motion sickness	1	0	1
	Tinnitus	13	0	12
	Vertigo	17	0	14
Endocrine disorders	Inappropriate antidiuretic hormone secretior	17	0	12
	Hypothyroidism	1	0	1
Eye disorders	Cataract	1	0	1
	Xerophthalmia	1	0	1
	Lacrimonal disorder	1	0	1
	Eye pain	4	0	3
	Ocular discomfort	1	0	1

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Eye disorders	Angle closure glaucoma	1	0	1
	Glaucoma	5	0	2
	Conjunctivitis	1	0	0
	Ocular hyperaemia	1	0	1
	Blepharospasm	1	0	1
	Oculogyration	3	0	2
	Mydriasis	24	0	16
	Eye rolling	1	0	0
	Eyelid sensory disorder	1	0	1
	Photophobia	5	0	5
	Blindness	1	0	1
	Accommodation disorder	1	0	1
	Xanthopsia	1	0	1
	Diplopia	5	0	4
	Photopsia	1	0	1
	Vision blurred	11	0	9
	Visual disturbance	30	0	26
	Scotoma	1	0	0
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	2	0	2
	Pancreatitis acute	1	0	1
	Gastric disorder	1	0	1
	Gastrointestinal disorder	1	0	1
	Rectal haemorrhage	1	0	1
	Haematemesis	3	0	0
	Melaena	1	0	0
	Colitis ulcerative	1	0	1
	Gastritis	1	0	1
	Enteritis	2	0	1
	Oesophagitis	1	0	1
	Diarrhoea	32	1	26

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Gastrointestinal disorders	Constipation	14	0	12
	Frequent bowel movements	1	0	1
	Irritable bowel syndrome	1	0	1
	Ileus paralytic	1	0	1
	Dyspepsia	11	0	9
	Abnormal faeces	2	0	2
	Flatulence	2	0	2
	Abdominal pain	12	0	10
	Abdominal pain upper	1	0	1
	Abdominal discomfort	2	0	2
	Dysphagia	5	0	4
	Faecal incontinence	1	0	1
	Stomach discomfort	2	0	2
	Nausea	141	0	116
	Vomiting	83	1	65
	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
	Dry mouth	18	0	16
	Salivary hypersecretion	4	0	4
	Glossitis	4	0	1
	Tongue disorder	2	0	2
	Tongue ulceration	1	0	1
	Tongue oedema	5	0	5
	General disorders and administration site conditions	Hyperthermia malignant	1	0
Chills		23	0	14
Feeling cold		1	0	0
Feeling hot		2	0	1
Feeling hot and cold		3	0	2
Pyrexia		20	1	5

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General disorders and administration site conditions	Death	1	1	0
	Death neonatal	1	1	1
	Sudden death	6	6	1
	Asthenia	19	0	15
	Fatigue	51	0	36
	Malaise	22	1	16
	Gait disturbance	10	0	6
	Chest discomfort	1	0	1
	Condition aggravated	5	0	4
	Feeling abnormal	8	0	8
	Feeling jittery	3	0	3
	Hunger	1	0	1
	Influenza like illness	7	0	6
	Irritability	9	0	7
	Multi-organ failure	1	1	0
	Thirst	3	0	3
	Face oedema	6	0	4
	Gravitational oedema	3	0	2
	Oedema	5	0	1
	Oedema peripheral	5	0	2
	Pitting oedema	1	0	0
	Chest pain	11	0	9
	Pain	10	0	8
	Drug interaction	9	0	0
	Drug effect decreased	2	0	1
	Drug ineffective	32	2	25
	Drug withdrawal syndrome	109	0	99
	Drug withdrawal syndrome neonatal	11	0	8
Therapeutic response decreased	1	0	0	
Hepatobiliary disorders	Cholecystitis	1	0	0
	Jaundice	3	0	2
	Hepatic function abnormal	14	1	7
	Hepatic failure	4	1	1
	Hepatitis	5	1	4
	Hepatitis fulminant	1	0	0



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Hepatobiliary disorders	Hepatocellular damage	1	0	0
Immune system disorders	Anaphylactic shock	1	0	1
	Anaphylactoid reaction	3	0	3
Infections and infestations	Bacterial infection	1	0	0
	Cellulitis	1	0	1
	Candidiasis	1	0	0
	Genital candidiasis	1	0	1
	Pneumonia	1	0	1
	Sepsis	1	1	0
	Rash pustular	1	0	0
	Nasopharyngitis	1	0	1
	Pharyngitis	3	0	3
	Gastritis viral	1	0	1
	Gastroenteritis viral	1	0	1
	Injury, poisoning and procedural complications	Drug toxicity	1	1
Poisoning		1	0	1
Drug exposure during pregnancy		9	1	6
Subdural haemorrhage		1	0	1
Fall		6	0	0
Head injury		2	0	0
Contusion		2	0	1
Chillblains		1	0	0
Heat stroke		1	1	0
Medication error		3	0	0
Accidental overdose		1	0	1
Intentional overdose		8	1	7
Overdose		10	0	5
Investigations		Cardiac murmur	1	0
	Cardiac electrophysiologic study abnormal	1	0	1
	Electrocardiogram QT prolonged	6	1	3
	Electrocardiogram abnormal	2	0	1
	Heart rate increased	2	0	2
	Blood pressure decreased	2	0	2
	Blood pressure increased	5	0	5
	Blood prolactin increased	1	0	0



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Investigations	Blood testosterone increased	1	0	0
	Blood creatine phosphokinase increased	5	1	1
	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
	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	10	0	5
	Antinuclear antibody positive	2	0	0
	Blood cholesterol increased	2	0	0
	Total cholesterol/HDL ratio decreased	1	0	0
	Blood triglycerides increased	2	0	1
	Intraocular pressure increased	1	0	1
	Weight decreased	8	0	6
	Weight increased	12	0	10
	C-reactive protein increased	1	0	0
	Semen abnormal	1	0	1
	Antidepressant drug level above therapeutic	1	0	1
	Antipsychotic drug level increased	1	0	0
	Drug level decreased	2	0	0
	Drug level increased	3	0	0
	Blood phosphorus decreased	1	0	0
Metabolism and nutrition disorders	Acidosis	2	1	0
	Anorexia	28	1	23
	Decreased appetite	1	0	1
	Food craving	1	0	1

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Metabolism and nutrition disorders	Increased appetite	2	0	1
	Feeding disorder neonatal	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	7	1	2
	Hypernatraemia	2	0	1
	Hyponatraemia	86	1	53
	Dehydration	5	0	3
	Fluid retention	2	0	2
	Alcohol intolerance	1	0	1
	Diabetes mellitus	1	0	1
	Gestational diabetes	1	0	1
	Hyperglycaemia	1	0	1
	Hypoglycaemia	5	0	2
	Musculoskeletal and connective tissue disorders	Jaw disorder	1	0
Systemic lupus erythematosus		1	0	1
Arthritis		6	0	3
Arthralgia		10	0	7
Joint stiffness		1	0	1
Osteoarthritis		2	0	1
Myalgia		28	0	22
Muscle spasms		7	0	4
Muscle tightness		2	0	2
Muscle twitching		14	0	8
Hypertonia neonatal		1	0	1
Muscle rigidity		4	0	1
Torticollis		1	0	0
Trismus		3	0	2
Muscular weakness		2	0	1
Rhabdomyolysis		4	1	1

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Musculoskeletal and connective tissue disorders	Back pain	2	0	2
	Mobility decreased	2	0	0
	Musculoskeletal stiffness	4	0	3
	Pain in extremity	2	0	2
Nervous system disorders	Cerebrovascular accident	3	0	3
	Haemorrhagic stroke	2	0	2
	Cerebrovascular disorder	3	1	2
	Facial palsy	1	0	1
	Encephalopathy	4	0	3
	Drug withdrawal headache	1	0	1
	Headache	94	0	71
	Migraine	5	0	2
	Migraine with aura	1	0	1
	Benign intracranial hypertension	1	0	1
	Brain oedema	1	0	0
	Amnesia	15	0	11
	Memory impairment	3	0	0
	Cognitive disorder	2	0	2
	Disturbance in attention	14	0	9
	Mental impairment	1	0	1
	Choreoathetosis	4	0	4
	Akathisia	25	1	16
	Bradykinesia	1	0	1
	Dyskinesia	14	0	7
	Extrapyramidal disorder	6	0	4
	Hyperkinesia	5	0	3
	Hypokinesia	1	0	0
	Movement disorder	2	0	1
	Psychomotor hyperactivity	2	0	1
	Tardive dyskinesia	8	0	4
	Dystonia	15	0	9
	Opisthotonus	1	0	1
	Paresis	1	0	1
	Parkinsonism	4	0	2
Tremor	77	0	45	

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VENLAFAXINE HYDROCHLORIDE		Layer 1 of 1		
Nervous system disorders	Hyperreflexia	8	0	4
	Hyporeflexia	1	0	1
	Reflexes abnormal	1	0	0
	Balance disorder	6	0	2
	Coordination abnormal	35	0	29
	Dysstasia	3	0	3
	Nystagmus	3	0	1
	Coma	4	0	1
	Consciousness fluctuating	2	0	1
	Depressed level of consciousness	5	0	1
	Lethargy	4	0	2
	Loss of consciousness	6	1	4
	Sedation	2	0	1
	Somnolence	37	0	26
	Stupor	1	0	1
	Syncope	25	0	16
	Syncope vasovagal	1	0	0
	Motor dysfunction	1	0	1
	Clonus	1	0	0
	Dizziness	97	0	77
	Head discomfort	2	0	2
	Myoclonus	3	0	0
	Tongue biting	1	0	0
	Hyperaesthesia	5	0	4
	Hypoaesthesia	12	0	11
	Paraesthesia	46	0	40
	Dysgeusia	6	0	6
	Restless legs syndrome	1	0	1
	Sensory disturbance	5	0	4
	Dysarthria	6	0	6
	Dysphasia	1	0	0
	Incoherent	1	0	0
	Speech disorder	3	0	1
	Tunnel vision	1	0	1
Visual field defect	2	0	2	

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Nervous system disorders	Horner's syndrome	1	0	1
	Hypertonia	23	0	10
	Neuroleptic malignant syndrome	6	1	0
	Serotonin syndrome	42	0	12
	Muscle contractions involuntary	1	0	0
	Myasthenia gravis	1	0	0
	Neuropathy	1	0	1
	Neuropathy peripheral	1	0	1
	Petit mal epilepsy	1	0	1
	Convulsion neonatal	1	0	0
	Grand mal convulsion	10	0	3
	Convulsion	49	0	25
	Convulsive threshold lowered	1	0	1
	Drug withdrawal convulsions	1	0	0
	Epilepsy	4	0	4
	Status epilepticus	2	0	2
	Tonic convulsion	1	0	1
	Circadian rhythm sleep disorder	1	0	0
	Hypersomnia	1	0	1
	Poor quality sleep	2	0	2
Pregnancy, puerperium and perinatal conditions	Intra-uterine death	1	0	1
	Premature labour	1	0	1
	Premature separation of placenta	1	0	1
	Pre-eclampsia	2	0	2
	Pregnancy induced hypertension	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
	Psychiatric disorders	Neurosis	1	0
Obsessive-compulsive disorder		1	0	1
Agitation		73	0	54



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Psychiatric disorders	Agitation neonatal	2	0	2
	Anxiety	49	0	31
	Nervousness	8	0	6
	Stress	1	0	0
	Tension	1	0	1
	Fear	1	0	1
	Panic disorder	1	0	1
	Panic attack	7	0	5
	Catatonia	1	0	0
	Decreased activity	1	0	1
	Restlessness	5	0	2
	Automatism	3	0	3
	Bruxism	7	0	6
	Posturing	1	0	1
	Stereotypy	1	0	0
	Confusional state	51	0	31
	Disorientation	15	0	10
	Delirium	17	0	10
	Depression	28	0	20
	Depression suicidal	1	0	0
	Major depression	1	0	0
	Decreased interest	1	0	0
	Depressed mood	2	0	2
	Tearfulness	3	0	2
	Depersonalisation	15	0	13
	Delusion	5	0	5
	Derealisation	1	0	0
	Hallucination	31	0	17
	Hallucination, auditory	3	0	2
	Hallucination, visual	1	0	1
	Hallucinations, mixed	1	0	1
	Thinking abnormal	17	0	12
	Eating disorder	2	0	1
	Hypomania	2	0	1
Mania	13	0	9	



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VENLAFAXINE HYDROCHLORIDE		Layer 1 of 1		
Psychiatric disorders	Affect lability	7	0	5
	Inappropriate affect	1	0	0
	Anger	9	0	7
	Crying	4	0	4
	Dysphoria	2	0	1
	Elevated mood	1	0	0
	Emotional disorder	2	0	2
	Euphoric mood	5	0	4
	Mood altered	2	0	2
	Mood swings	6	0	6
	Affective disorder	1	0	0
	Apathy	5	0	5
	Aggression	35	0	24
	Disturbance in social behaviour	1	0	1
	Homicidal ideation	19	0	9
	Hostility	3	0	3
	Paranoia	7	0	5
	Personality change	2	0	1
	Violent ideation	3	0	2
	Abnormal behaviour	5	0	5
	Hypervigilance	1	0	0
	Psychiatric symptom	1	0	1
	Mental status changes	1	0	0
	Alcohol problem	1	0	1
	Alcoholism	1	0	0
	Drug dependence	1	0	1
	Psychotic disorder	10	0	6
	Schizophreniform disorder	1	0	1
	Schizophrenia	1	0	0
	Anorgasmia	4	0	3
	Premature ejaculation	1	0	1
	Libido decreased	9	0	8
	Loss of libido	3	0	2
	Insomnia	46	0	37
Abnormal dreams	8	0	7	

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VENLAFAXINE HYDROCHLORIDE		Layer 1 of 1		
Psychiatric disorders	Abnormal sleep-related event	4	0	0
	Nightmare	28	0	25
	Sleep walking	3	0	1
	Sleep disorder	2	0	1
	Conversion disorder	1	0	1
	Completed suicide	12	12	9
	Intentional self-injury	1	0	0
	Self injurious behaviour	1	0	0
	Self-injurious ideation	1	0	1
	Suicidal behaviour	1	0	0
	Suicidal ideation	69	1	45
	Suicide attempt	53	2	36
	Renal and urinary disorders	Oliguria	1	0
Renal failure acute		3	0	0
Renal impairment		4	0	2
Urethral disorder		1	0	1
Dysuria		3	0	3
Micturition disorder		7	0	7
Micturition urgency		1	0	0
Pollakiuria		4	0	4
Urinary hesitation		1	0	1
Urinary incontinence		8	0	6
Urinary retention		10	0	9
Haematuria		2	0	2
Nocturia		1	0	1
Polyuria		1	0	1
Nephrolithiasis		2	0	1
Reproductive system and breast disorders	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	1	0	0
	Amenorrhoea	5	0	1

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Reproductive system and breast disorders	Menorrhagia	3	0	2
	Metrorrhagia	3	0	1
	Polycystic ovaries	1	0	0
	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	3	0	1
	Priapism	1	0	1
	Sexual dysfunction	4	0	4
	Spermatorrhoea	1	0	1
	Testicular disorder	1	0	1
	Testicular pain	1	0	0
	Uterine haemorrhage	1	0	0
	Vaginal haemorrhage	1	0	1
Respiratory, thoracic and mediastinal disorders	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 embolism	2	1	1
	Apnoea	3	0	2
	Dyspnoea	16	1	9
	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
	Respiratory disorder	1	0	0
Increased upper airway secretion	1	0	1	

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Respiratory, thoracic and mediastinal disorders	Sneezing	1	0	1
	Throat tightness	2	0	0
	Yawning	9	0	8
	Epistaxis	2	0	1
	Oropharyngeal swelling	1	0	0
	Pharyngeal oedema	1	0	1
Skin and subcutaneous tissue disorders	Angioedema	10	0	8
	Urticaria	18	0	15
	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
	Systemic lupus erythematosus rash	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
	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	3	0	1
	Pruritus	36	0	26
	Pruritus generalised	1	0	0
	Rash pruritic	1	0	0
	Dermatitis psoriasiform	1	0	1
	Psoriasis	1	0	0
	Rash follicular	1	0	1
	Rash	24	0	18
	Rash maculo-papular	13	0	11
	Acne	2	0	2
Alopecia	6	0	4	
Anhidrosis	1	0	1	

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Skin and subcutaneous tissue disorders	Cold sweat	3	0	2
	Hyperhidrosis	82	0	61
	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
Social circumstances	Activities of daily living impaired	1	0	1
Surgical and medical procedures	Therapy regimen changed	11	0	7
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	6	1	2
	Shock	1	1	0
	Hypotension	16	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	19	0	14
	Hot flush	4	0	3
	Pallor	4	0	2
	Haemorrhage	1	0	1
	Hypertension	44	0	29
	Maternal hypertension affecting foetus	1	0	0
	Vasculitis	1	0	1