

Case Series Drug Analysis Print
Name: FOI 21/1254 Gardasil Vaccine VAP

Report Run Date: 10-Dec-2021

Data Lock Date: 09-Dec-2021 18:30:03

Earliest Reaction Date: 05-May-2006

MedDRA Version: MedDRA 24.1

FOI 21/1254 Gardasil Vaccine VAP: All UK Spontaneously received Adverse Drug Reaction (ADR) reports associated with the Gardasil Vaccine

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
Pernicious anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	5	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	22	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	2	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	5	0
Blood disorders SOC TOTAL	44	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	23	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Postural orthostatic tachycardia syndrome	33	0
Tachycardia	12	0
<i>Supraventricular arrhythmias</i>		
Sinus arrhythmia	1	0
Sinus tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	1
Pulseless electrical activity	1	0
Cardiac disorders SOC TOTAL	76	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	4	0
<i>Inborn errors of bilirubin metabolism</i>		
Gilbert's syndrome	1	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	1	0
Congenital disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	6	0
<i>Hearing disorders NEC</i>		
Auditory disorder	1	0
<i>Hearing losses</i>		
Deafness	5	0
Deafness transitory	1	0
Hypoacusis	6	0
<i>Hyperacusia</i>		
Hyperacusis	9	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	5	0
Vertigo	4	0
Ear disorders SOC TOTAL	38	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	2	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Lymphocytic hypophysitis	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	1	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	2	0
Hypothyroidism	4	0
Endocrine disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
Eyelid ptosis	3	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Iris adhesions	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
Swelling of eyelid	7	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye pain	7	0
Eye swelling	5	0
Periorbital pain	1	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Eye pruritus	3	0
Ocular hyperaemia	3	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle paresis	1	0
Eye movement disorder	18	0
Ophthalmoplegia	1	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	1	0
Photophobia	20	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	5	0
Pupillary disorder	1	0
<i>Visual disorders NEC</i>		
Diplopia	7	0
Halo vision	1	0
Photopsia	3	0
Vision blurred	59	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	3	0
Blindness transient	9	0
Visual acuity reduced	1	0
Visual impairment	29	0
Eye disorders SOC TOTAL	204	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	1	0
Crohn's disease	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	32	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	5	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	9	0
Flatulence	2	0
<i>Gastric and oesophageal haemorrhages</i>		
Oesophageal haemorrhage	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	2	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	61	0
Abdominal pain lower	9	0
Abdominal pain upper	49	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	9	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	5	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	4	0
Gastrointestinal disorder	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Gastrointestinal motility disorder	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Oesophageal mucosal hyperplasia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	14	0
Dysphagia	9	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	9	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival ulceration	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Inguinal hernias</i>		
Inguinal hernia	2	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	1	0
Coeliac disease	7	0
Malabsorption	1	0
<i>Nausea and vomiting symptoms</i>		
Cyclic vomiting syndrome	1	0
Nausea	430	0
Retching	4	0
Vomiting	180	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	2	0
Haematochezia	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
Lip dry	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Lip blister	1	0
Uvulitis	1	0
<i>Oral soft tissue signs and symptoms</i>		
Lip erythema	1	0
Oral discomfort	1	0
Oral mucosal blistering	1	0
Oral mucosal eruption	1	0
Oral pain	1	0
Paraesthesia oral	13	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	11	0
<i>Peritoneal and retroperitoneal disorders</i>		
Intra-abdominal fluid collection	1	0
<i>Stomatitis and ulceration</i>		
Lip ulceration	1	0
Mouth ulceration	5	0
<i>Tongue disorders</i>		
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	4	0
Tongue coated	1	0
Gastrointestinal disorders SOC TOTAL	923	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	67	0
Chronic fatigue syndrome	33	0
Fatigue	219	0
Malaise	224	0
<i>Body temperature altered</i>		
Temperature regulation disorder	7	0
<i>Complications associated with device NEC</i>		
Injury associated with device	1	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	152	0
<i>Feelings and sensations NEC</i>		
Chills	30	0
Feeling abnormal	38	0
Feeling cold	19	0
Feeling drunk	1	0
Feeling hot	59	0
Feeling jittery	2	0
Feeling of body temperature change	4	0
Sensation of foreign body	1	0
Temperature intolerance	6	0
Thirst	3	0
<i>Gait disturbances</i>		
Gait disturbance	12	0
Gait inability	11	0
Loss of control of legs	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	6	0
Crying	5	0
Exercise tolerance decreased	5	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Glassy eyes	1	0
Ill-defined disorder	4	0
Illness	25	0
Induration	1	0
Influenza like illness	19	0
Local reaction	5	0
Peripheral swelling	99	0
Screaming	1	0
Secretion discharge	1	0
Swelling	14	0
Swelling face	20	0
<i>Healing abnormal NEC</i>		
Impaired healing	2	0
<i>Hernias NEC</i>		
Hernia	1	0
<i>Inflammations</i>		
Inflammation	6	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Serositis	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	2	0
Injection site bruising	4	0
Injection site discomfort	1	0
Injection site erythema	11	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	5	0
Injection site induration	2	0
Injection site inflammation	1	0
Injection site joint pain	2	0
Injection site mass	12	0
Injection site movement impairment	1	0
Injection site nerve damage	1	0
Injection site oedema	1	0
Injection site pain	30	0
Injection site paraesthesia	1	0
Injection site pruritus	8	0
Injection site rash	1	0
Injection site reaction	1	0
Injection site swelling	20	0
Injection site warmth	2	0
<i>Mass conditions NEC</i>		
Mass	2	0
<i>Mucosal findings abnormal</i>		
Mucosal ulceration	1	0
<i>Oedema NEC</i>		
Face oedema	1	0
Localised oedema	1	0
Oedema peripheral	5	0
<i>Pain and discomfort NEC</i>		
Axillary pain	2	0
Chest discomfort	21	0
Chest pain	36	0
Discomfort	11	0
Facial pain	1	0
Non-cardiac chest pain	2	0
Pain	70	0
Tenderness	3	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	9	0
Adverse event	1	0
Adverse reaction	2	0
Drug ineffective	2	0
Drug resistance	1	0
Immediate post-injection reaction	1	0
Therapeutic response unexpected	1	0
Vaccination failure	1	0
<i>Trophic disorders</i>		
Atrophy	1	0
Hyperplasia	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site bruising	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	10	0
Vaccination site inflammation	2	0
Vaccination site irritation	1	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	2	0
Vaccination site movement impairment	2	0
Vaccination site nerve damage	1	0
Vaccination site pain	13	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	4	0
Vaccination site rash	3	0
Vaccination site swelling	11	0
Vaccination site warmth	2	0
General disorders SOC TOTAL	1454	1

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Hepatitis	1	0
Hepatitis acute	1	0
Hepatic disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	32	0
Multiple allergies	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	1	0
Food allergy	2	0
Reaction to excipient	2	0
Rubber sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	31	0
Anaphylactic shock	2	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	6	0
<i>Immune and associated conditions NEC</i>		
Decreased immune responsiveness	1	0
Immune system disorder	7	0
Immune system disorders SOC TOTAL	88	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	1	0
Appendicitis	1	0
Appendicitis perforated	1	0
Gastroenteritis	1	0
Gastrointestinal infection	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Candida infections</i>		
Candida infection	1	0
Vulvovaginal candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	4	0
Subdural abscess	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	0
<i>Female reproductive tract infections</i>		
Amniotic cavity infection	1	0
Pelvic inflammatory disease	1	0
Vulvovaginitis	1	0
<i>Haemophilus infections</i>		
Haemophilus infection	1	0
<i>Herpes viral infections</i>		
Herpes zoster	5	0
Oral herpes	1	0
<i>Infections NEC</i>		
Infection	2	0
Infection susceptibility increased	1	0
Injection site infection	1	0
Localised infection	1	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	2	0
<i>Papilloma viral infections</i>		
Papilloma viral infection	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	1	0
Sepsis	1	0
Septic rash	1	0
<i>Staphylococcal infections</i>		
Staphylococcal infection	1	0
<i>Streptococcal infections</i>		

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Infections		
Infections cont'd		
Beta haemolytic streptococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	7	0
Pharyngitis	3	0
Sinusitis	2	0
Tonsillitis	3	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	2	0
Post viral fatigue syndrome	11	0
Viral infection	4	0
Infections SOC TOTAL	80	0

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Reaction Name	Total	Fatal
Injuries		
<i>Bone and joint injuries NEC</i>		
Joint injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	4	0
Foetal exposure during pregnancy	4	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	1	0
<i>Non-site specific injuries NEC</i>		
Fall	7	0
Injury	1	0
Wound haemorrhage	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Poisoning and toxicity</i>		
Metal poisoning	1	0
Poisoning	1	0
<i>Product administration errors and issues</i>		
Expired product administered	1	0
Extra dose administered	2	0
Inappropriate schedule of product administration	5	0
Product administered at inappropriate site	3	0
Wrong product administered	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Contusion	10	0
<i>Thermal burns</i>		
Thermal burn	1	0
<i>Vaccination related complications</i>		
Vaccination complication	8	0
Injuries SOC TOTAL	55	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
Heart sounds abnormal	1	0
<i>ECG investigations</i>		
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	3	0
Heart rate decreased	5	0
Heart rate increased	18	0
Heart rate irregular	6	0
Pulse abnormal	3	0
Pulse absent	2	0
Pulse pressure decreased	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin A increased	1	0
<i>Liver function analyses</i>		
Blood bilirubin increased	1	0
Hepatic enzyme increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	3	0
Blood magnesium decreased	1	0
Blood selenium decreased	1	0
Blood zinc decreased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature decreased	1	0
Body temperature fluctuation	3	0
Body temperature increased	15	0
Respiratory rate increased	5	0
Weight decreased	3	0
Weight increased	1	0
<i>Pituitary analyses anterior</i>		
Blood growth hormone abnormal	1	0
Blood thyroid stimulating hormone abnormal	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Protein analyses NEC</i>		
Blood albumin abnormal	1	0
C-reactive protein increased	2	0
Protein total abnormal	1	0
<i>Reproductive hormone analyses</i>		
Progesterone increased	1	0
<i>Reproductive organ and breast histopathology procedures</i>		
Smear cervix abnormal	1	0

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Investigations Investigations cont'd		
<i>Tissue enzyme analyses NEC</i>		
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
<i>Toxicology laboratory analyses</i>		
Blood chromium decreased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure immeasurable	1	0
Blood pressure increased	2	0
<i>Vitamin analyses</i>		
Vitamin B12 increased	1	0
Vitamin D decreased	3	0
Investigations SOC TOTAL	113	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	3	0
Decreased appetite	28	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	5	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	6	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	2	0
Gluten sensitivity	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	10	0
Abnormal weight gain	1	0
Feeding disorder	3	0
Weight gain poor	1	0
<i>Hyperglycaemic conditions NEC</i>		
Insulin resistance	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Lactic acidosis	1	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<i>Mineral related disorders NEC</i>		
Mineral deficiency	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	2	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
<i>Vitamin deficiencies NEC</i>		
Multi-vitamin deficiency	2	0
<i>Water soluble vitamin deficiencies</i>		
Vitamin B12 deficiency	4	0
Metabolic disorders SOC TOTAL	82	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
Arthropathy	3	0
Seronegative arthritis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	5	0
Coccydynia	1	0
Pain in jaw	4	0
Spinal pain	2	0
<i>Cartilage disorders</i>		
Osteochondrosis	1	0
<i>Extremity deformities</i>		
Finger deformity	1	0
Foot deformity	1	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
Joint lock	1	0
Periarthritis	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	99	0
Joint noise	2	0
Joint range of motion decreased	1	0
Joint stiffness	7	0
Joint swelling	13	0
<i>Ligament disorders</i>		
Ligament pain	1	0
<i>Muscle pains</i>		
Fibromyalgia	3	0
Myalgia	47	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle fatigue	5	0
Muscle spasms	27	0
Muscle tightness	2	0
Muscle twitching	22	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	18	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	56	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Growth retardation	1	0
Mobility decreased	5	0
Muscle contracture	1	0
Musculoskeletal stiffness	31	0
Posture abnormal	1	0
Weight bearing difficulty	4	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	29	0
Growing pains	1	0
Limb discomfort	17	0
Musculoskeletal chest pain	5	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Musculoskeletal discomfort	2	0
Musculoskeletal pain	3	0
Neck pain	30	0
Pain in extremity	163	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
Groin pain	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	2	0
<i>Synovial disorders</i>		
Synovitis	1	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	631	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour metastatic	1	0
<i>Leukaemias acute lymphocytic</i>		
T-cell type acute leukaemia	1	1
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
<i>Reproductive neoplasms male benign NEC</i>		
Penile wart	1	0
<i>Skin neoplasms benign</i>		
Anogenital warts	2	0
Skin papilloma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	10	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	3	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	2	0
Autonomic neuropathy	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem stroke	1	0
Cerebral thrombosis	1	0
Cerebrovascular accident	2	0
Lacunar infarction	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	4	0
Balance disorder	8	0
Coordination abnormal	5	0
Dysstasia	6	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	3	0
Dyslexia	1	0
Dyspraxia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Consciousness fluctuating	2	0
Depressed level of consciousness	6	0
Lethargy	63	0
Loss of consciousness	33	0
Somnolence	46	0
Syncope	277	0
<i>Disturbances in sleep phase rhythm</i>		
Irregular sleep wake rhythm disorder	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	36	0
Fine motor skill dysfunction	1	0
Hypokinesia	4	0
Motor dysfunction	4	0
Movement disorder	7	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
Noninfective encephalitis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	3	0
Facial paralysis	3	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	8	0
<i>Headaches NEC</i>		
Cluster headache	5	0
Headache	463	0
Tension headache	3	0
<i>Increased intracranial pressure disorders</i>		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	1	0
Memory loss (excl dementia)		
Amnesia	11	0
Memory impairment	10	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	9	0
Disturbance in attention	22	0
Mental impairment	2	0
Migraine headaches		
Migraine	29	0
Migraine with aura	2	0
Mononeuropathies		
Peroneal nerve palsy	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	1	0
Muscle tone abnormal		
Hypotonia	10	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	10	0
Narcolepsy	3	0
Nervous system cysts and polyps		
Colloid brain cyst	1	0
Pineal gland cyst	1	0
Nervous system disorders NEC		
Cerebral disorder	1	0
Nervous system disorder	5	0
Neurologic visual problems NEC		
Tunnel vision	1	0
Neurological signs and symptoms NEC		
Dizziness	688	0
Dizziness exertional	1	0
Dizziness postural	13	0
Head discomfort	4	0
Hyporesponsive to stimuli	1	0
Myoclonus	1	0
Patient elopement	1	0
Presyncope	21	0
Slow response to stimuli	3	0
Unresponsive to stimuli	25	0
Olfactory nerve disorders		
Anosmia	1	0
Paraesthesias and dysaesthesias		
Burning sensation	7	0
Hyperaesthesia	6	0
Hypoaesthesia	86	0
Paraesthesia	101	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	2	0
Hemiparesis	6	0
Hemiplegia	1	0
Monoplegia	10	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Paralysis	11	0
Paraplegia	1	0
Peripheral paralysis	1	0
Quadriplegia	1	0
Peripheral neuropathies NEC		
Peripheral sensory neuropathy	1	0
Seizures and seizure disorders NEC		
Change in seizure presentation	1	0
Epilepsy	9	0
Febrile convulsion	1	0
Partial seizures	1	0
Psychogenic seizure	1	0
Seizure	59	0
Seizure anoxic	1	0
Seizure like phenomena	4	0
Tonic clonic movements	5	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Ageusia	1	0
Complex regional pain syndrome	8	0
Dysgeusia	2	0
Neuralgia	4	0
Sensory disturbance	7	0
Sensory loss	10	0
Taste disorder	2	0
Speech and language abnormalities		
Dysarthria	7	0
Incoherent	1	0
Slow speech	4	0
Speech disorder	4	0
Spinal cord and nerve root disorders NEC		
Spinal cord oedema	1	0
Structural brain disorders NEC		
Brain injury	1	0
Tremor (excl congenital)		
Tremor	64	0
Nervous system disorders SOC TOTAL	2326	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
Abortion threatened	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	1
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	2	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
<i>Maternal complications of pregnancy NEC</i>		
Cervical incompetence	1	0
Pregnancy conditions SOC TOTAL	8	1

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Reaction Name	Total	Fatal
<i>Product label issues</i>		
Product lot number issue	1	0
<i>Product quality issues NEC</i>		
Product origin unknown	5	0
Product quality issue	1	0
Product substitution issue	1	0
null SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	7	0
Staring	1	0
<i>Affect alterations NEC</i>		
Inappropriate affect	1	0
<i>Anxiety disorders NEC</i>		
Generalised anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	2	0
Anxiety	32	0
Nervousness	2	0
Stress	2	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Disinhibition	1	0
Paranoia	2	0
Personality change	7	0
Social avoidant behaviour	1	0
<i>Bipolar disorders</i>		
Bipolar disorder	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	2	0
<i>Confusion and disorientation</i>		
Confusional state	19	0
Disorientation	14	0
<i>Deliria</i>		
Delirium	2	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	14	0
Depression suicidal	4	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	16	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Eating disorders NEC</i>		
Anorexia nervosa	1	0
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Emotional disorder	3	0
Emotional distress	6	0
Mood altered	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Claustrophobia	1	0
Phobia	1	0
Social anxiety disorder	3	0
<i>Fluctuating mood symptoms</i>		
Mood swings	3	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	3	0
Hallucination, auditory	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Hallucination, visual	1	0
Increased physical activity levels		
Restlessness	1	0
Mental disorders NEC		
Mental disorder	4	0
Mental status changes	1	0
Mood alterations with depressive symptoms		
Decreased interest	1	0
Depressed mood	4	0
Tearfulness	12	0
Mood disorders NEC		
Apathy	3	0
Listless	1	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive disorder	1	0
Panic attacks and disorders		
Panic attack	5	0
Panic reaction	3	0
Parasomnias		
Sleep terror	1	0
Perception disturbances NEC		
Deja vu	1	0
Near death experience	1	0
Personality disorders NEC		
Self esteem decreased	1	0
Personality disorders with anxious behaviour (Cluster C)		
Dependent personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	1	0
Psychiatric symptoms NEC		
Psychiatric symptom	1	0
Psychotic disorder NEC		
Psychotic disorder	1	0
Sleep disorders NEC		
Sleep disorder	12	0
Somatic symptom disorders		
Conversion disorder	4	0
Somatic symptom disorder	1	0
Speech and language usage disturbances		
Logorrhoea	1	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	3	0
Suicidal ideation	4	0
Suicide attempt	1	0
Thinking disturbances		
Thought blocking	1	0
Tic disorders		
Tic	2	0
Psychiatric disorders SOC TOTAL	239	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Dysuria	1	0
Incontinence	1	0
Urinary incontinence	11	0
Urinary retention	2	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Bladder infections and inflammations</i>		
Cystitis noninfective	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	3	0
<i>Genitourinary tract infections and inflammations NEC</i>		
Urinary tract inflammation	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal vasculitis	1	0
<i>Urinary abnormalities</i>		
Proteinuria	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Gynaecomastia	1	0
Nipple disorder	1	0
<i>Breast signs and symptoms</i>		
Breast pain	1	0
Nipple pain	1	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	3	0
<i>Menopausal effects NEC</i>		
Premature menopause	2	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	7	0
Menstrual disorder	7	0
Menstruation irregular	12	0
Premenstrual pain	1	0
Premenstrual syndrome	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	11	0
Menstruation delayed	3	0
Oligomenorrhoea	2	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	13	0
Polymenorrhoea	1	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Polycystic ovaries	2	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovarian disorder	1	0
Ovarian failure	3	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	3	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	1	0
Infertility	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	2	0
Vulval ulceration	1	0
<i>Vulvovaginal signs and symptoms</i>		
Coital bleeding	1	0
Reproductive & breast disorders SOC TOTAL	83	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	66	0
Grunting	1	0
Hyperventilation	16	0
Hypopnoea	8	0
Respiration abnormal	2	0
Respiratory arrest	4	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	9	0
Bronchospasm	5	0
Obstructive airways disorder	2	0
Wheezing	5	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	14	0
Productive cough	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Vocal cord disorder	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngospasm	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pleuritic pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	11	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	2	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pneumothorax	1	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Respiratory disorder	1	1
Respiratory tract inflammation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking sensation	1	0
Dry throat	1	0
Dysphonia	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	30	0
Rhinorrhoea	2	0
Sinus pain	2	0
Throat irritation	9	0
Throat tightness	8	0
Respiratory disorders SOC TOTAL	219	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	4	0
Acne cystic	1	0
<i>Alopecias</i>		
Alopecia	13	0
Alopecia areata	2	0
Diffuse alopecia	1	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	5	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	43	0
Hyperhidrosis	32	0
Miliaria	1	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	2	0
Erythema multiforme	3	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	6	0
Pain of skin	2	0
Papule	4	0
Scab	1	0
Skin burning sensation	1	0
Skin discolouration	27	0
Skin reaction	3	0
Skin tightness	3	0
Skin warm	14	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	14	0
Dermatitis contact	1	0
Eczema	6	0
Eczema nummular	1	0
Skin irritation	4	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	52	0
Palmar erythema	1	0
<i>Exfoliative conditions</i>		
Skin exfoliation	3	0
<i>Hyperpigmentation disorders</i>		
Melanoderma	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Papulosquamous conditions</i>		
Pityriasis rosea	2	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	6	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Pruritus NEC</i>		
Pruritus	56	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	5	0
Petechiae	4	0
Purpura	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	104	0
Rash erythematous	21	0
Rash macular	19	0
Rash maculo-papular	2	0
Rash papular	3	0
Rash pruritic	15	0
Rash vesicular	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
Umbilical discharge	1	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin striae	2	0
<i>Skin preneoplastic conditions NEC</i>		
Precancerous skin lesion	1	0
<i>Skin vasculitides</i>		
Vasculitic rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	19	0
<i>Urticarias</i>		
Urticaria	86	0
Skin disorders SOC TOTAL	613	0

Case Series Drug Analysis Print

Name: FOI 21/1254 Gardasil Vaccine VAP

Report Run Date: 10-Dec-2021
Earliest Reaction Date: 05-May-2006

Data Lock Date: 09-Dec-2021 18:30:03
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	2	0
Loss of personal independence in daily activities	6	0
Physical disability	1	0
<i>Educational issues</i>		
Educational problem	1	0
Social circumstances SOC TOTAL	10	0

Case Series Drug Analysis Print

Name: FOI 21/1254 Gardasil Vaccine VAP

Report Run Date: 10-Dec-2021

Data Lock Date: 09-Dec-2021 18:30:03

Earliest Reaction Date: 05-May-2006

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Hernia repairs</i>		
Inguinal hernia repair	1	0
<i>Obstetric therapeutic procedures</i>		
Vacuum extractor delivery	1	0
<i>Ovarian therapeutic procedures</i>		
Oophorectomy	1	0
<i>Psychiatric therapies</i>		
Antidepressant therapy	1	0
Surgical & medical procedures SOC TOTAL	4	0

Case Series Drug Analysis Print

Name: FOI 21/1254 Gardasil Vaccine VAP

Report Run Date: 10-Dec-2021
 Earliest Reaction Date: 05-May-2006

Data Lock Date: 09-Dec-2021 18:30:03
 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Venous haemorrhage	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
Vasodilatation	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	11	0
Flushing	27	0
Hot flush	4	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	31	0
Poor peripheral circulation	3	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	126	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Orthostatic hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	13	0
Orthostatic hypotension	1	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	229	0
TOTAL REACTIONS FOR DRUG	7592	5
TOTAL REPORTS	2462	
TOTAL FATAL OUTCOME REPORTS		5