

Case Series Drug Analysis Print

Name: MMR Vaccine Drug Analysis Print

Report Run Date: 18-Apr-2017
Data Lock Date: 17-Apr-2017 19:00:04
Earliest Reaction Date: 11-Mar-1997
MedDRA Version: MedDRA 19.1

MMR Vaccine Drug Analysis Print: MMR vaccine Drugs Analysis Print. All UK, suspected spontaneous reports associated with the MMR vaccine and the brands Pluserix, Immravax, Priorix, M-M-R-II and MMRVaxPro between 01/01/2007 and 31/03/2017.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	2	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
<i>Haematological disorders</i>		
Placental transfusion syndrome	1	0
<i>Leukocytoses NEC</i>		
Monocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenitis	1	0
Lymphadenopathy	58	0
<i>Marrow depression and hypoplastic anaemias</i>		
Cytopenia	1	0
Pancytopenia	1	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	1	0
<i>Spleen disorders</i>		
Splenomegaly	2	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenic purpura	20	0
Thrombocytopenia	1	0
Thrombocytopenic purpura	2	0
Blood disorders SOC TOTAL	94	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	14	0
Palpitations	3	0
<i>Noninfectious myocarditis</i>		
Myocarditis	2	1
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Pulmonary valvular disorders</i>		
Pulmonary valve stenosis	2	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	5	0
Tachycardia	4	0
<i>Supraventricular arrhythmias</i>		
Atrial tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Cardiac disorders SOC TOTAL	36	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Anorectal disorders congenital</i>		
Preternatural anus	2	0
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 21	2	0
<i>Bladder disorders congenital</i>		
Congenital vesicoureteric reflux	1	0
<i>Cardiac septal defects congenital</i>		
Atrioventricular septal defect	2	0
<i>Chromosomal abnormalities NEC</i>		
Gene mutation	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
Congenital cyst	1	0
VACTERL syndrome	2	0
<i>External ear disorders congenital</i>		
Anomaly of external ear congenital	1	0
<i>Eyelid disorders congenital</i>		
Eyelid ptosis congenital	2	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Congenital umbilical hernia	1	0
<i>Great vessel disorders congenital</i>		
Double outlet right ventricle	2	0
<i>Immune system abnormalities congenital</i>		
Combined immunodeficiency	1	0
Primary immunodeficiency syndrome	2	0
<i>Inborn errors of amino acid metabolism</i>		
Phenylketonuria	1	0
<i>Laryngeal and tracheal disorders congenital</i>		
Laryngomalacia	1	0
<i>Lens disorders congenital</i>		
Cataract congenital	1	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Hydrocele	2	0
Hypospadias	2	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Congenital foot malformation	1	0
Developmental hip dysplasia	3	0
Limb hypoplasia congenital	2	0
Limb reduction defect	2	0
Talipes	3	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Plagiocephaly	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Spine malformation	2	0
<i>Persistent foetal circulation disorders</i>		
Patent ductus arteriosus	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital pneumonia	1	0
Pulmonary aplasia	2	0
Pulmonary hypoplasia	2	0
<i>Renal disorders congenital</i>		
Congenital cystic kidney disease	2	0

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Congenital disorders Congenital disorders cont'd		
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Congenital naevus	1	0
Congenital skin dimples	2	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	2	0
Congenital disorders SOC TOTAL	56	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	3	0
Ear pain	7	0
Otorrhoea	2	0
<i>Eustachian tube disorders</i>		
Eustachian tube dysfunction	1	0
<i>Hearing losses</i>		
Deafness	5	0
Deafness bilateral	1	0
Deafness neurosensory	3	0
Deafness unilateral	1	0
Hypoacusis	7	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Vertigo	4	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane disorder	1	0
Ear disorders SOC TOTAL	37	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Blindness (excl colour blindness)</i>		
Blindness	1	0
Blindness cortical	1	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis allergic	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	3	0
<i>Lens structural change, deposit and degeneration (excl cataracts)</i>		
Aphakia	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	2	0
Eyelid oedema	5	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye pain	11	0
Eye swelling	17	0
Ocular discomfort	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	5	0
Eye inflammation	1	0
Eye pruritus	2	0
Ocular hyperaemia	9	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	9	0
Strabismus	4	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	16	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	1	0
<i>Pupil disorders</i>		
Mydriasis	2	0
Pupil fixed	3	0
Pupils unequal	1	0
<i>Refractive and accommodative disorders</i>		
Altered visual depth perception	1	0
<i>Visual disorders NEC</i>		
Diplopia	2	0
Vision blurred	3	0
Visual impairment	6	0
Eye disorders SOC TOTAL	115	0

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Gastrointestinal disorders		
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	88	0
Diarrhoea neonatal	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	2	0
Faeces discoloured	5	0
Faeces soft	1	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	7	0
Flatulence	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	21	0
Abdominal pain lower	2	0
Abdominal pain upper	16	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	8	0
Gastrooesophageal reflux disease	3	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i>		
Gastrointestinal necrosis	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	5	0
Anal incontinence	2	0
Dysphagia	4	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	2	0
<i>Gingival pains</i>		
Gingival pain	2	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile vomiting	2	0
Nausea	36	0
Regurgitation	1	0
Retching	2	0
Vomiting	146	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Vomiting projectile	5	0
Non-site specific gastrointestinal haemorrhages		
Haematemesis	1	0
Oesophagitis (excl infective)		
Oesophagitis	1	0
Oral dryness and saliva altered		
Salivary hypersecretion	3	0
Oral soft tissue disorders NEC		
Chapped lips	1	0
Lip ulceration	1	0
Oral disorder	2	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	0
Oral soft tissue pain and paraesthesia		
Oral pain	4	0
Paraesthesia oral	8	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	2	0
Oral mucosal blistering	5	0
Oral mucosal eruption	2	0
Oral soft tissue swelling and oedema		
Gingival swelling	2	0
Lip swelling	19	0
Mouth swelling	4	0
Salivary gland disorders NEC		
Salivary gland mass	1	0
Salivary gland pain	1	0
Salivary gland enlargements		
Parotid gland enlargement	15	0
Stomatitis and ulceration		
Mouth ulceration	3	0
Tongue disorders		
Tongue ulceration	1	0
Tongue signs and symptoms		
Glossodynia	1	0
Swollen tongue	5	0
Tongue coated	1	0
Tongue discolouration	1	0
Umbilical hernias		
Umbilical hernia	2	0
Gastrointestinal disorders SOC TOTAL	463	0

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Reaction Name	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	2	0
<i>Asthenic conditions</i>		
Asthenia	13	0
Chronic fatigue syndrome	1	0
Fatigue	49	0
Malaise	124	0
<i>Death and sudden death</i>		
Death	7	7
Sudden death	2	2
<i>Febrile disorders</i>		
Pyrexia	406	0
<i>Feelings and sensations NEC</i>		
Chills	18	0
Feeling abnormal	13	0
Feeling drunk	1	0
Feeling hot	22	0
Feeling of body temperature change	3	0
Hangover	1	0
Thirst	1	0
Thirst decreased	1	0
<i>Gait disturbances</i>		
Abasia	8	0
Gait disturbance	10	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crepitations	1	0
Crying	28	0
Developmental delay	5	0
Foaming at mouth	1	0
Glassy eyes	1	0
Ill-defined disorder	1	0
Induration	3	0
Influenza like illness	21	0
Local reaction	11	0
Local swelling	30	0
Peripheral swelling	52	0
Secretion discharge	2	0
Swelling	14	0
<i>Inflammations</i>		
Inflammation	13	0
<i>Infusion site reactions</i>		
Infusion site erythema	1	0
<i>Injection site reactions</i>		
Injection site bruising	5	0
Injection site discolouration	3	0
Injection site erythema	40	0
Injection site induration	6	0
Injection site inflammation	10	0
Injection site irritation	1	0
Injection site mass	7	0
Injection site oedema	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site pain	16	0
Injection site pruritus	5	0
Injection site rash	12	0
Injection site reaction	14	0
Injection site swelling	42	0
Injection site urticaria	1	0
Injection site vesicles	2	0
Injection site warmth	5	0
Interactions		
Drug interaction	1	0
Mass conditions NEC		
Mass	3	0
Nodule	1	0
Mucosal findings abnormal		
Mucosal haemorrhage	1	0
Mucous membrane disorder	1	0
Oedema NEC		
Face oedema	1	0
Oedema peripheral	3	0
Pain and discomfort NEC		
Chest discomfort	5	0
Chest pain	9	0
Discomfort	15	0
Facial pain	1	0
Non-cardiac chest pain	1	0
Pain	34	0
Tenderness	11	0
Therapeutic and nontherapeutic responses		
Drug ineffective	7	0
Therapy non-responder	23	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	3	0
Vaccination site bruising	1	0
Vaccination site discomfort	3	0
Vaccination site erythema	17	0
Vaccination site induration	4	0
Vaccination site inflammation	2	0
Vaccination site joint erythema	1	0
Vaccination site mass	3	0
Vaccination site pain	14	0
Vaccination site pruritus	3	0
Vaccination site rash	8	0
Vaccination site swelling	13	0
Vaccination site warmth	9	0
General disorders SOC TOTAL	1236	9

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	19	0
Multiple allergies	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
Food allergy	2	0
Milk allergy	1	0
Reaction to drug excipients	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	25	1
Anaphylactic shock	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immunisation reaction	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Primary immunodeficiency syndromes</i>		
Selective IgG subclass deficiency	1	0
Immune system disorders SOC TOTAL	57	1

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	3	0
<i>Bacterial infections NEC</i>		
Cellulitis	35	0
Citrobacter sepsis	1	0
Injection site cellulitis	3	0
Vaccination site cellulitis	5	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
<i>Candida infections</i>		
Vulvovaginal candidiasis	1	0
<i>Cardiac infections</i>		
Pericarditis infective	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	10	2
Meningitis	2	0
Meningitis aseptic	2	0
Panencephalitis	1	1
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
Parotitis	2	0
<i>Ear infections</i>		
Ear infection	13	0
Labyrinthitis	1	0
Mastoiditis	1	0
Otitis media	7	0
Otitis media acute	1	0
Otitis media chronic	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	12	0
Eye infection	4	0
<i>Haemophilus infections</i>		
Haemophilus sepsis	1	0
<i>Hepatitis viral infections</i>		
Gianotti-Crosti syndrome	1	0
<i>Herpes viral infections</i>		
Human herpesvirus 6 infection	1	0
Human herpesvirus 7 infection	1	0
Oral herpes	2	0
Varicella	4	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	4	0
Injection site abscess	4	0
Injection site infection	2	0
Respiratory tract infection	1	0
Toxic shock syndrome	1	0
Vaccination site infection	2	0
Vestibulitis	1	0
<i>Infectious transmissions</i>		
Infection via vaccinee	1	0

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Infections		
Infections cont'd		
Transmission of an infectious agent via product	1	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
Influenza	2	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	11	0
Pneumonia	4	0
<i>Male reproductive tract infections</i>		
Epididymitis	1	0
Orchitis	6	0
<i>Mumps viral infections</i>		
Encephalitis mumps	1	0
Mumps	28	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Rubella viral infections</i>		
Rubella	2	0
<i>Rubeola viral infections</i>		
Measles	38	0
Measles post vaccine	5	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	4	1
Sepsis neonatal	1	0
Septic shock	1	0
<i>Skin structures and soft tissue infections</i>		
Pyoderma	1	0
Skin infection	2	0
<i>Staphylococcal infections</i>		
Staphylococcal abscess	1	0
<i>Tuberculous infections</i>		
Erythema induratum	1	0
<i>Upper respiratory tract infections</i>		
Croup infectious	3	0
Nasopharyngitis	18	0
Pharyngitis	4	0
Rhinitis	7	0
Tonsillitis	9	0
Upper respiratory tract infection	8	0
<i>Urinary tract infections</i>		
Urinary tract infection	4	0
<i>Viral infections NEC</i>		
Bronchiolitis	2	0
Ear infection viral	1	0
Gastroenteritis viral	1	0
Meningitis viral	2	0
Post viral fatigue syndrome	2	0
Viral infection	8	0
Viral rash	1	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	319	4

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Reaction Name	Total	Fatal
Injuries		
<i>Conditions caused by cold</i>		
Chillblains	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	65	0
Foetal exposure during pregnancy	38	0
Maternal exposure before pregnancy	15	0
Maternal exposure timing unspecified	3	0
<i>Limb fractures and dislocations</i>		
Foot fracture	1	0
<i>Maladministrations</i>		
Drug administration error	1	0
Expired product administered	1	0
Extra dose administered	2	0
Inappropriate schedule of drug administration	6	0
Wrong drug administered	3	0
<i>Medication errors NEC</i>		
Medication error	7	0
Vaccination error	2	0
<i>Medication monitoring errors</i>		
Labelled drug-disease interaction medication error	1	0
Labelled drug-drug interaction medication error	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
<i>Product use issues NEC</i>		
Drug administered to patient of inappropriate age	2	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	2	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Contusion	21	0
Laceration	2	0
<i>Vaccination related complications</i>		
Vaccination complication	2	0
Vaccination failure	7	0
Injuries SOC TOTAL	188	0

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Rheumatoid factor increased	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
Blood glucose fluctuation	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	5	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate decreased	2	0
Foetal monitoring abnormal	3	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	3	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	4	0
Heart rate increased	5	0
Heart rate irregular	3	0
Pulse abnormal	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	1	0
<i>Immunology analyses NEC</i>		
Antibody test negative	1	0
Immunology test abnormal	1	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test abnormal	1	0
Quality of life decreased	1	0
<i>Liver function analyses</i>		
Liver function test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	2	0
Body temperature abnormal	1	0
Body temperature decreased	3	0
Body temperature fluctuation	3	0
Body temperature increased	59	0
Breath sounds abnormal	2	0
Grip strength decreased	1	0
Head circumference abnormal	1	0
Lymph node palpable	1	0
Respiratory rate increased	4	0
Weight decreased	4	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count abnormal	1	0
Platelet count decreased	5	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	4	0
<i>Red blood cell analyses</i>		
Haemoglobin S	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
<i>Urinalysis NEC</i>		
Protein urine	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Blood pressure increased	7	0
<i>Virus identification and serology</i>		
Measles antibody negative	1	0
Measles antibody positive	1	0
Mumps antibody test negative	1	0
Rubella antibody negative	5	0
Rubella antibody positive	1	0
<i>White blood cell analyses</i>		
Lymphocyte morphology abnormal	1	0
Investigations SOC TOTAL	152	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	124	0
Diet refusal	1	0
Hypophagia	3	0
<i>Cell metabolism disorders NEC</i>		
Mitochondrial cytopathy	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	2	0
Type 1 diabetes mellitus	3	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	6	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Cow's milk intolerance	2	0
Food intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	2	0
Failure to thrive	1	0
Feeding disorder	4	0
Food aversion	2	0
Poor feeding infant	2	0
Weight gain poor	1	0
<i>Iron deficiencies</i>		
Iron deficiency	1	0
<i>Total fluid volume decreased</i>		
Dehydration	3	0
Metabolic disorders SOC TOTAL	164	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	5	0
Arthritis reactive	1	0
Arthropathy	1	0
<i>Bone disorders NEC</i>		
Exostosis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Pain in jaw	2	0
<i>Connective tissue disorders NEC</i>		
Myofascitis	1	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	54	0
Joint crepitation	1	0
Joint stiffness	5	0
Joint swelling	12	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle pains</i>		
Myalgia	22	0
<i>Muscle related signs and symptoms NEC</i>		
Diastasis recti abdominis	1	0
Muscle atrophy	1	0
Muscle spasms	3	0
Muscle twitching	5	0
<i>Muscle tone abnormalities</i>		
Floppy infant	3	0
Muscle rigidity	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	10	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	10	0
Limb discomfort	2	0
Musculoskeletal chest pain	1	0
Musculoskeletal pain	4	0
Neck pain	7	0
Pain in extremity	37	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Growth retardation	1	0
Mobility decreased	2	0
Musculoskeletal stiffness	19	0
Posture abnormal	1	0
Weight bearing difficulty	6	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
Neck mass	1	0
Muscle & tissue disorders SOC TOTAL	227	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
Neoplasms SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	3	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Central nervous system vascular disorders NEC		
Vertebrobasilar insufficiency	1	0
Coordination and balance disturbances		
Ataxia	2	0
Balance disorder	8	0
Coordination abnormal	3	0
Dysstasia	1	0
Hand-eye coordination impaired	1	0
Cortical dysfunction NEC		
Aphasia	4	0
Dyslexia	1	0
Dyspraxia	3	0
Developmental disorders cognitive		
Autism	16	0
Disturbances in consciousness NEC		
Altered state of consciousness	2	0
Consciousness fluctuating	1	0
Depressed level of consciousness	1	0
Lethargy	46	0
Loss of consciousness	14	0
Somnolence	40	0
Syncope	38	0
Dyskinesias and movement disorders NEC		
Clumsiness	1	0
Dyskinesia	8	0
Fine motor skill dysfunction	1	0
Hypokinesia	2	0
Psychomotor hyperactivity	4	0
Dystonias		
Opisthotonus	2	0
Encephalopathies NEC		
Encephalopathy	6	0
Encephalopathy neonatal	1	0
Hypoxic-ischaemic encephalopathy	1	0
Facial cranial nerve disorders		
Facial paralysis	4	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	7	0
Headaches NEC		
Headache	69	0
Sinus headache	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	1	0
Memory loss (excl dementia)		
Amnesia	3	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	3	0
Disturbance in attention	7	0
Mental impairment	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Migraine headaches		
Migraine	6	0
Mononeuropathies		
Mononeuropathy multiplex	1	0
Muscle tone abnormal		
Hypotonia	22	0
Narcolepsy and hypersomnia		
Hypersomnia	3	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Neurological signs and symptoms NEC		
Decorticate posture	1	0
Dizziness	28	0
Dizziness postural	1	0
Drooling	1	0
Exaggerated startle response	1	0
Head discomfort	3	0
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Meningism	1	0
Myoclonus	1	0
Neurological decompensation	1	0
Neurological symptom	2	0
Presyncope	6	0
Slow response to stimuli	1	0
Unresponsive to stimuli	19	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	1	0
Paraesthesias and dysaesthesias		
Burning sensation	2	0
Hyperaesthesia	2	0
Hypoaesthesia	9	0
Paraesthesia	19	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	3	0
Paresis	1	0
Seizures and seizure disorders NEC		
Convulsion in childhood	1	0
Convulsion neonatal	1	0
Epilepsy	7	0
Febrile convulsion	36	0
Idiopathic generalised epilepsy	2	0
Partial seizures	4	0
Seizure	43	0
Seizure anoxic	2	0
Seizure like phenomena	1	0
Status epilepticus	2	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Dysgeusia	2	0
Hypogeusia	1	0
Neuralgia	1	0
Sensory disturbance	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Sensory loss	2	0
Speech and language abnormalities		
Aphonia	1	0
Dysarthria	2	0
Speech disorder	6	0
Speech disorder developmental	3	0
Structural brain disorders NEC		
Brain injury	2	0
Tremor (excl congenital)		
Tremor	20	0
Nervous system disorders SOC TOTAL	590	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Blighted ovum	1	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	2	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	36	0
Abortion threatened	2	0
Imminent abortion	1	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Oligohydramnios	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
Foetal hypokinesia	2	0
<i>Foetal growth complications</i>		
Foetal growth restriction	6	0
<i>Foetal position and presentation abnormalities</i>		
Breech presentation	4	0
Face presentation	1	0
High foetal head	1	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	7	0
<i>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	1	0
<i>High risk pregnancies</i>		
High risk pregnancy	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Gestational hypertension	1	0
Pre-eclampsia	4	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	2	0
Premature labour	2	0
Premature rupture of membranes	1	0
Prolonged labour	9	0
<i>Maternal complications of delivery NEC</i>		
Breech delivery	1	0
<i>Maternal complications of labour NEC</i>		
Labour complication	5	0
<i>Maternal complications of pregnancy NEC</i>		
Complication of pregnancy	1	0
Vomiting in pregnancy	1	0
<i>Multiple pregnancies</i>		
Multiple pregnancy	2	0
<i>Neonatal gastrointestinal disorders</i>		
Meconium increased	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Postpartum haemorrhage	2	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	1
Stillbirth	2	2
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	113	3

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product quality issue	3	0
null SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	15	0
Breath holding	1	0
Staring	5	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
<i>Anxiety symptoms</i>		
Agitation	3	0
Anxiety	8	0
Nervousness	4	0
Stress	1	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit/hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	4	0
Antisocial behaviour	1	0
Personality change	2	0
Social avoidant behaviour	4	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	4	0
Disorientation	8	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	2	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	1	0
Insomnia	28	0
Middle insomnia	2	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Dysphoria	1	0
Emotional disorder	3	0
Emotional distress	10	0
Irritability	46	0
Moaning	2	0
Mood altered	5	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Increased physical activity levels</i>		
Restlessness	8	0
<i>Learning disorders</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Learning disability	2	0
Mental disorders NEC		
Mental disorder	2	0
Mental status changes	2	0
Mood alterations with depressive symptoms		
Anhedonia	1	0
Decreased interest	1	0
Depressed mood	5	0
Tearfulness	13	0
Mood disorders NEC		
Apathy	1	0
Listless	4	0
Obsessive-compulsive disorders and symptoms		
Body dysmorphic disorder	1	0
Obsessive-compulsive symptom	1	0
Trichotillomania	1	0
Panic attacks and disorders		
Panic attack	2	0
Parasomnias		
Nightmare	1	0
Sleep terror	1	0
Perception disturbances		
Hallucination	6	0
Hallucination, visual	2	0
Time perception altered	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	4	0
Psychiatric elimination disorders		
Enuresis	2	0
Psychiatric symptoms NEC		
Decreased eye contact	3	0
Psychotic disorder NEC		
Psychotic disorder	1	0
Sleep disorders NEC		
Sleep disorder	15	0
Somatic symptom disorders		
Conversion disorder	1	0
Speech articulation and rhythm disturbances		
Screaming	16	0
Stereotypies and automatisms		
Head banging	3	0
Stereotypy	1	0
Thinking disturbances		
Thinking abnormal	1	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	275	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Incontinence	1	0
Micturition urgency	1	0
Pollakiuria	1	0
Urinary incontinence	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Renal structural abnormalities and trauma</i>		
Pyelocaliectasis	1	0
<i>Urinary abnormalities</i>		
Haematuria	3	0
Proteinuria	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast infections and inflammations</i>		
Nipple inflammation	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	2	0
Genital swelling	1	0
Oedema genital	1	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	2	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	5	0
Testicular swelling	13	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	6	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal discomfort	1	0
Reproductive & breast disorders SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	26	0
Hypopnoea	4	0
Respiratory arrest	6	0
Respiratory depression	1	0
Respiratory distress	2	0
Sleep apnoea syndrome	3	0
<i>Bronchospasm and obstruction</i>		
Asthma	5	0
Wheezing	11	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Hypoxia	2	0
<i>Coughing and associated symptoms</i>		
Cough	54	0
Productive cough	2	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Lower respiratory tract inflammation	1	0
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	13	0
Nasal pruritus	1	0
<i>Neonatal hypoxic conditions</i>		
Neonatal respiratory distress syndrome	3	0
<i>Newborn respiratory disorders NEC</i>		
Bronchopulmonary dysplasia	1	0
Transient tachypnoea of the newborn	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal disorder	1	0
Pharyngeal erythema	4	0
Pharyngeal oedema	6	0
Pharyngeal paraesthesia	1	0
Tonsillar hypertrophy	4	0
Tonsillar inflammation	2	0
Velopharyngeal incompetence	2	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Dysphonia	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	31	0
Rhinorrhoea	32	0
Sinus pain	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Throat irritation	1	0
Throat tightness	1	0
Yawning	1	0
Vascular pulmonary disorders NEC		
Pulmonary arteriopathy	2	0
Respiratory disorders SOC TOTAL	239	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Angioedemas</i>		
Angioedema	6	0
Swelling face	30	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	7	0
Hyperhidrosis	16	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	18	0
Blood blister	2	0
Dermatitis bullous	1	0
Erythema multiforme	11	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	3	0
Pain of skin	2	0
Papule	3	0
Scab	1	0
Skin burning sensation	1	0
Skin discolouration	7	0
Skin disorder	2	0
Skin fissures	1	0
Skin induration	3	0
Skin lesion	2	0
Skin reaction	5	0
Skin tightness	1	0
Skin warm	11	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	9	0
Dermatitis atopic	1	0
Dermatitis diaper	3	0
Eczema	19	0
Eczema infantile	1	0
Eczema weeping	1	0
Skin irritation	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Drug reaction with eosinophilia and systemic symptoms	1	0
<i>Erythemas</i>		
Erythema	92	0
Rash erythematous	22	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Hypopigmentation disorders</i>		
Vitiligo	2	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	1	0
<i>Pigmentation changes NEC</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	40	0
Pruritus generalised	2	0
Rash pruritic	10	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	5	0
Petechiae	9	0
Purpura	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	196	0
Rash generalised	66	0
Rash macular	32	0
Rash maculo-papular	19	0
Rash morbilliform	77	0
Rash papular	12	0
Rash rubelliform	1	0
Rash vesicular	3	0
<i>Scaly conditions</i>		
Pityriasis	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	1	0
<i>Skin vasculitides</i>		
Vasculitic rash	1	0
<i>Urticarias</i>		
Urticaria	62	0
Skin disorders SOC TOTAL	837	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	2	0
Impaired work ability	2	0
Mental disability	1	0
Walking disability	2	0
<i>Educational issues</i>		
Educational problem	1	0
<i>Family and partner issues</i>		
Multiple birth sibling	2	0
<i>Social issues NEC</i>		
Contraindication to vaccination	5	0
Social circumstances SOC TOTAL	15	0

Case Series Drug Analysis Print

Name: MMR Vaccine Drug Analysis Print

Report Run Date: 18-Apr-2017

Data Lock Date: 17-Apr-2017 19:00:04

Earliest Reaction Date: 11-Mar-1997

MedDRA Version: MedDRA 19.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Induced abortions</i>		
Abortion induced	4	0
<i>Lymphoid tissue therapeutic procedures</i>		
Splenectomy	1	0
<i>Middle ear therapeutic procedures</i>		
Ear tube insertion	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	20	0
Episiotomy	1	0
Forceps delivery	1	0
Labour induction	1	0
Labour stimulation	1	0
<i>Therapeutic procedures NEC</i>		
Surgery	1	0
<i>Tonsillar therapeutic procedures</i>		
Adenoidectomy	1	0
Tonsillectomy	1	0
Surgical & medical procedures SOC TOTAL	34	0

Case Series Drug Analysis Print

Name: MMR Vaccine Drug Analysis Print

Report Run Date: 18-Apr-2017
 Earliest Reaction Date: 11-Mar-1997

Data Lock Date: 17-Apr-2017 19:00:04
 MedDRA Version: MedDRA 19.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
<i>Arterial inflammations</i>		
Kawasaki's disease	2	0
Temporal arteritis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	3	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Haemorrhage	7	0
<i>Non-site specific vascular disorders NEC</i>		
Superficial vein prominence	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	2	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	3	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	50	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	79	0
TOTAL REACTIONS FOR DRUG	5388	18
TOTAL REPORTS	1692	
TOTAL FATAL OUTCOME REPORTS		18