Report Run Date: 09-Aug-2021

08-Aug-2021 18:30:04 Data Lock Date:

Earliest Reaction Date: 15-Jan-2000 MedDRA 24.0 MedDRA Version:

FOI 21/877 - MMR All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated with the MMR vaccine in 2019 Vaccine DAP 2019:

Report Run Date: 09-Aug-2021, Page 1

Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	2	0
Leukopenias NEC		
Lymphopenia	2	0
Lymphatic system disorders NEC		
Lymphadenopathy	9	0
Thrombocytopenias		
Immune thrombocytopenia	2	0
Thrombocytopenia	1	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	17	l o

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac disorders NEC		
Cardiovascular disorder	1	0
Cardiac signs and symptoms NEC		
Palpitations	1	0
Endocarditis NEC		
Endocarditis noninfective	1	1
Heart failures NEC		
Cardiac failure	1	0
Pericardial disorders NEC		
Pericardial effusion	1	0
Ventricular arrhythmias and cardiac arrest		
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	6	1

Name: FOI 21/877 - MMR Vaccine DAP 2019

Report Run Date: 09-Aug-2021 Data Lock Date: 08-Aug-2021 18:30:04 Earliest Reaction Date: 15-Jan-2000 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Congenital disorders		
Immune system abnormalities congenital		
Primary immunodeficiency syndrome	1	0
Lymphatic system disorders congenital		
Cystic lymphangioma	1	1
Congenital disorders SOC TOTAL	2	1

Report Run Date: 09-Aug-2021, Page 4

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear congestion		1 0
Ear pain		1 0
Ear swelling		1 0
Otorrhoea		1 0
Hearing losses		
Deafness		2 0
Deafness transitory		1 0
Hypoacusis		1 0
Tympanic membrane disorders (excl infections)		
Tympanic membrane perforation		1 0
Ear disorders SOC TOTAL		9 0

Reaction Name	Total	Fatal
Eye disorders		
Lacrimation disorders		
Lacrimation increased	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Swelling of eyelid	1	0
Ocular disorders NEC		
Eye swelling	1	0
Periorbital swelling	1	0
Ocular infections, inflammations and associated manifestations		
Ocular hyperaemia	3	0
Ocular nerve and muscle disorders		
Eye movement disorder	1	0
Opsoclonus myoclonus	1	0
Ocular sensation disorders		
Photophobia	1	0
Visual disorders NEC		
Vision blurred	1	0
Visual impairment and blindness (excl colour blindness)		
Cortical visual impairment	1	0
Visual impairment	2	0
Eye disorders SOC TOTAL	14	0

Earliest Reaction Date: 15-Jan-2000	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders		
Colitis (excl infective)		
Inflammatory bowel disease	1	0
Diarrhoea (excl infective)		
Diarrhoea	22	0
Dyspeptic signs and symptoms		
Dyspepsia	1	0
Faecal abnormalities NEC		
Faeces discoloured	1	0
Mucous stools	1	0
Flatulence, bloating and distension		
Abdominal distension	1	0
Gastrointestinal and abdominal pains (exc	l oral and throat)	
Abdominal pain		0
Abdominal pain upper	6	0
Gastrointestinal atonic and hypomotility dis	sorders NEC	
Constipation	3	3 O
Gastrooesophageal reflux disease	2	0
Gastrointestinal disorders NEC		
Gastrointestinal disorder	1	0
Gastrointestinal dyskinetic disorders		
Gastrointestinal motility disorder	1	0
Gastrointestinal signs and symptoms NEC		
Anal incontinence	1	0
Dysphagia	1	0
Intestinal haemorrhages		
Rectal haemorrhage	1	0
Nausea and vomiting symptoms		
Nausea	8	3 0
Vomiting	28	
Vomiting projectile	2	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	0
Oral soft tissue signs and symptoms		
Oral pain	1	0
Oral soft tissue swelling and oedema		
Lip swelling	4	l 0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland enlargements		
Parotid gland enlargement	1	0
Stomatitis and ulceration		
Mouth ulceration	1	0
Tongue disorders		
Tongue geographic	1	0
Tongue signs and symptoms		
Tongue eruption	2	0
Gastrointestinal disorders SOC TOTAL	94	ıl o

	Version: MedDRA 24.0	
Reaction Name	Total	Fatal
General disorders		
Asthenic conditions		
Asthenia	4	. 0
Fatigue	11	0
Malaise	19	0
Febrile disorders		
Pyrexia	169	0
Feelings and sensations NEC		
Chills	7	0
Feeling abnormal		
Feeling hot	2	0
Feeling of body temperature change	1	1
Gait disturbances		
Gait disturbance	2	. 0
Gait inability	2	o o
General signs and symptoms NEC	2	
Condition aggravated	1	0
Crying	8	-
Developmental delay	1	
		1
Developmental regression	2	0
High-pitched crying	2 2 7	
Illness		
Influenza like illness	3	0
Peripheral swelling	18	0
Screaming	2	0
Swelling	13	
Swelling face	4	. 0
Inflammations		
Inflammation	4	0
Injection site reactions		
Injection site bruising	2	1
Injection site discolouration		
Injection site discomfort	1	_
Injection site erythema	3	0
Injection site indentation	1	0
Injection site inflammation	1	
Injection site mass	2	
Injection site pain	1	
Injection site pruritus	3 2	0
Injection site rash	3	0
Injection site swelling	2	. 0
Injection site vesicles	1	
Injection site warmth	2	0
Pain and discomfort NEC		
Chest discomfort	1	0
Chest pain		0
Discomfort	1	0
Non-cardiac chest pain		0
Pain	18	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse event	1	
Vaccination failure	2	
Vaccination site reactions		

Name: FOI 21/877 - MMR Vaccine DAP 2019

Report Run Date: 09-Aug-2021

Earliest Reaction Date: 15-Jan-2000

Data Lock Date: 08-Aug-2021 18:30:04

MedDRA Version: MedDRA 24.0

To

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	2	0
Vaccination site erythema	27	0
Vaccination site haematoma	1	0
Vaccination site induration	3	0
Vaccination site inflammation	3	0
Vaccination site mass	9	0
Vaccination site movement impairment	1	0
Vaccination site nodule	1	0
Vaccination site pain	6	0
Vaccination site pruritus	3	0
Vaccination site rash	7	0
Vaccination site reaction	1	0
Vaccination site swelling	28	0
Vaccination site urticaria	1	0
Vaccination site warmth	7	0
General disorders SOC TOTAL	434	0

Name: FOI 21/877 - MMR Vaccine DAP 2019

Reaction Name	Total	Fatal
Hepatic disorders		
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	1	0
Hepatocellular damage and hepatitis NEC		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergy to metals	1	0
Hypersensitivity	8	0
Allergies to foods, food additives, drugs and other chemicals		
Milk allergy	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	3	0
Immune and associated conditions NEC		
Decreased immune responsiveness	1	0
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	2	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	18	1

Earliest Reaction Date: 15-Jan-2000	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Infections		
Bacterial infections NEC		
Administration site cellulitis	1	0
Cellulitis	10	0
Injection site cellulitis	1	0
Vaccination site cellulitis	2	0
Candida infections		
Candida infection	1	0
Oral candidiasis	1	0
Central nervous system and spinal infections	1	
Encephalitis	3	0
Ear infections		
Ear infection	2	0
Eye and eyelid infections		
Conjunctivitis	6	0
Herpes viral infections		
Human herpesvirus 6 infection	1	0
Varicella	1	0
Infections NEC		
Abscess	1	0
Localised infection	1	0
Vaccination site infection	3	0
Infectious transmissions		
Infection transmission via personal contact	1	0
Influenza viral infections		
Influenza	1	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	2	0
Male reproductive tract infections		
Orchitis	1	0
Mumps viral infections		
Encephalitis mumps	1	0
Mumps	6	1
Rubella viral infections		
Encephalomyelitis rubella	1	0
Rubella	2	0
Rubeola viral infections		
Measles	13	0
Measles post vaccine	2	0
Sepsis, bacteraemia, viraemia and fungaemi	a NEC	
Septic shock	1	0
Skin structures and soft tissue infections		
Vaccination site pustule	1	0
Upper respiratory tract infections		
Croup infectious	2	
Nasopharyngitis	2	0
Rhinitis	1	0
Sinusitis	1	0
Tonsillitis	2	0
Upper respiratory tract infection	2	0
Viral infections NEC		
Encephalitis viral	1	0
Viral infection	2	0
Infections SOC TOTAL		1

Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Foetal exposure during pregnancy	1	0
Non-site specific injuries NEC		
Injury	1	0
Product administration errors and issues		
Booster dose missed	2	0
Inappropriate schedule of product administration	3	0
Incorrect dose administered	1	0
Product administered at inappropriate site	1	0
Site specific injuries NEC		
Central nervous system injury	1	0
Skin injuries NEC		
Contusion	6	0
Scar	1	0
Injuries SOC TOTAL	17	0

Reaction Name	Total	Fatal
Investigations		
Heart rate and pulse investigations		
Heart rate increased	1	0
Liver function analyses		
Transaminases increased	1	0
Physical examination procedures and organ system status		
Body temperature	1	0
Body temperature fluctuation	1	0
Body temperature increased	11	0
Respiratory rate increased	1	0
Platelet analyses		
Platelet count decreased	1	0
Toxicology laboratory analyses		
Blood aluminium increased	1	0
Blood heavy metal increased	1	0
Urinary tract function analyses NEC		
Urine output decreased	1	0
Virus identification and serology		
Mumps antibody test negative	2	0
Investigations SOC TOTAL	22	0

Earliest Reaction Date: 15-Jan-2000 MedDRA Version: MedDRA 24.0		
Reaction Name	_Total_	<u>Fatal</u>
Metabolic disorders		
Appetite disorders		
Decreased appetite	52	0
Hypophagia	1	0
Increased appetite	1	0
Fluid intake decreased		
Fluid intake reduced	1	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Food intolerance	1	0
General nutritional disorders NEC		
Feeding disorder	2	0
Hypoglycaemic conditions NEC		
Hypoglycaemia	1	0
Metabolic acidoses (excl diabetic acidoses)		
Metabolic acidosis	2	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Protein metabolism disorders NEC		
Hyperammonaemia	1	0
Sodium imbalance		
Hyponatraemia	1	0
Metabolic disorders SOC TOTAL	64	0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthropathy	1	0
Bone related signs and symptoms		
Pubic pain	1	0
Cartilage disorders		
Costochondritis	1	0
Joint related signs and symptoms		
Arthralgia	6	0
Joint stiffness	1	0
Joint swelling	2	0
Muscle pains		
Myalgia	2	0
Muscle tone abnormalities		
Floppy infant	1	0
Muscle weakness conditions		
Muscular weakness	4	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	1	0
Weight bearing difficulty	3	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Pain in extremity	12	0
Soft tissue disorders NEC		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	40	l o

Report Run Date: 09-Aug-2021 Data Lock Date: 08-Aug-2021 18:30:04

Earliest Reaction Date: 15-Jan-2000 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	1	0
Acute polyneuropathies		
Guillain-Barre syndrome	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral infarction	1	0
Choreiform movements		
Chorea	1	0
Coordination and balance disturbances		
Dysstasia	1	0
Cortical dysfunction NEC		
Aphasia	4	0
Sensory processing disorder	2	0
Disturbances in consciousness NEC		
Depressed level of consciousness	1	0
Lethargy	13	
Loss of consciousness	3	0
Somnolence	3	0
Syncope	2	0
Dyskinesias and movement disorders NEC		
Hypokinesia	1	0
Headaches NEC		
Headache	7	0
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	1	0
Mental impairment	1	0
Muscle tone abnormal		
Hypotonia	1	0
Nervous system disorders NEC		
Nervous system disorder	3	0
Neurological signs and symptoms NEC		
Dizziness	3	0
Dizziness postural	1	0
Inability to crawl	1	0
Infant irritability	2	0
Neurological decompensation	2	0
Neuromuscular disorders NEC		
Muscle spasticity	1	0
Paraesthesias and dysaesthesias		
Hypoaesthesia	6	0
Paraesthesia	3	
Paralysis and paresis (excl cranial nerve)		
Paralysis	3	0
Peripheral neuropathies NEC		
Polyneuropathy	1	0
Seizures and seizure disorders NEC		_
Epilepsy	1	0
Febrile convulsion	7	0
Myoclonic epilepsy	1	0
Partial seizures	2	0
Seizure	8	0
Sensory abnormalities NEC		Ŭ
Neuralgia Neuralgia	1	0

Reaction Name		Total	Fatal
Nervous system disorders co	nt'd		
Sensory loss		1	0
Sleep disturbances NEC			
Sleep deficit		1	0
Speech and language abnormalities			
Repetitive speech		1	0
Speech disorder		2	0
Structural brain disorders NEC			
Brain injury		1	0
Tremor (excl congenital)			
Tremor		4	0
Nervous system disorders SOC TOTAL		99	0

Name: FOI 21/877 - MMR Vaccine DAP 2019

Earliest Reaction Date: 15-Jan-2000 Me Reaction Name	dDRA Version: MedDRA 24.0 Total	Fatal
Psychiatric disorders	IOIAI	<u>i alai</u>
Abnormal behaviour NEC		
Abnormal behaviour	5	0
Staring		1
Affect alterations NEC		
Affect lability	1	0
Anxiety symptoms		
Agitation		0
Anxiety	2	o o
Nervousness	1	1
Attention deficit and disruptive behaviour disord		
Attention deficit hyperactivity disorder	1	0
Behaviour and socialisation disturbances		
Aggression	1	0
Personality change	5	
Social avoidant behaviour	2	
Communications disorders		
Communication disorder	1	0
Confusion and disorientation		
Disorientation	2	0
Deliria		
Delirium	1	0
Depressive disorders		
Depression	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	5	0
Dyssomnias		
Poor quality sleep	2	2 0
Eating disorders NEC		
Eating disorder	1	0
Emotional and mood disturbances NEC		
Emotional distress	2	
Frustration tolerance decreased	1	
Irritability	28	
Morose	1	0
Fear symptoms and phobic disorders (incl social	l phobia)	
Social anxiety disorder	1	0
Increased physical activity levels		
Restlessness	5	0
Learning disorders		_
Learning disability	1	0
Mental disorders NEC		
Mental disorder	2	2 0
Mood alterations with depressive symptoms		
Depressed mood		_
Tearfulness	1	0
Mood disorders NEC		
Affective disorder		
Listless	1	0
Parasomnias Nightmara		
Nightmare	2	2 0
Pervasive developmental disorders NEC	40	
Autism spectrum disorder	13	0
Psychiatric symptoms NEC		

Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric} disorders cont'd		
Decreased eye contact	1	0
Sleep disorders NEC		
Sleep disorder	7	0
Speech articulation and rhythm disturbances		
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	1	0
Head banging	1	0
Posturing	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	2	0
Self-injurious ideation	1	0
Thinking disturbances		
Intrusive thoughts	1	0
Psychiatric disorders SOC TOTAL	111	0

Name: FOI 21/877 - MMR Vaccine DAP 2019

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Urinary incontinence	1	0
Glomerulonephritis and nephrotic syndrome		
Nephrotic syndrome	1	0
Myoneurogenic bladder disorders		
Bladder dysfunction	1	0
Nephropathies and tubular disorders NEC		
Renal tubular disorder	2	0
Renal failure and impairment		
Renal impairment	1	0
Renal & urinary disorders SOC TOTAL	6	o l

Name: FOI 21/877 - MMR Vaccine DAP 2019

Report Run Date: 09-Aug-2021 Data Lock Date: 08-Aug-2021 18:30:04
Earliest Reaction Date: 15-Jan-2000 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menstruation and uterine bleeding NEC		
Menstrual disorder	1	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	1	0
Reproductive tract signs and symptoms NEC		
Pelvic pain	1	0
Reproductive & breast disorders SOC TOTAL	3	م ا

Rescrition Name Total Fata Respiratory disorders	
Breathing abnormalities Dyspnoea Hypopnoea 1 Irregular breathing Respiration abnormal Respiratory arrest Tachypnoea Bronchospasm and obstruction Wheezing Coughing and associated symptoms Cough Haemoptysis Lower respiratory tract inflammatory and immunologic conditions Alveolitis Nasal congestion and inflammations Nasal congestion and inflammations Nasal congestion Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion Parenchymal lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Pharyngeal inflammation 1 Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion 1 Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	L
Dyspnea	
Hypopnoea Irregular breathing Irregular breathing Respiration abnormal Respiratory arrest A Tachypnoea Inchospasm and obstruction Wheezing Coughing and associated symptoms Cough Haemoptysis Lower respiratory tract inflammatory and immunologic conditions Alveolitis Insal congestion and inflammations Nasal congestion Nasal congestion Nasal disorders NEC Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal inflammation Inosillar hypertrophy Pleural conditions NEC Pleural adhesion Inching disorders (excl infections and neoplasms) Pharyngeal inflammation Inosillar hypertrophy Pleural conditions NEC Pleural adhesion Inching disorders (excl infections NEC Pleural adhesion Inching disorders (excl infections NEC Pleural effusion NEC Pleural effusion Inching disorders (excl infections NEC Pleural effusion NEC Pleural effusion Inching disorders (excl infections NEC Pleural effusion NEC Pleural effusion Inching disorders (excl infections NEC Pleural effusion NEC Pleural effusion NEC	
Irregular breathing Respiration abnormal Respiratory arrest Tachypnoea Bronchospasm and obstruction Wheezing Coughing and associated symptoms Cough Haemoptysis Lower respiratory tract inflammatory and immunologic conditions Alveolitis Nasal congestion and inflammations Nasal congestion and inflammations Nasal disorders NEC Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion Parenchymal lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural adhesion Pneumothorax and pleural effusions NEC Pleural adhesion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	0
Respiration abnormal Respiratory arrest Atachypnoea Bronchospasm and obstruction Wheezing Coughing and associated symptoms Cough Haemoptysis Lower respiratory tract inflammatory and immunologic conditions Alveolitis Nasal congestion and inflammations Nasal congestion and inflammations Nasal disorders NEC Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural adhesion Pneumothorax and pleural effusions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	0
Respiratory arrest Tachypnoea 1 Bronchospasm and obstruction Wheezing Coughing and associated symptoms Cough Haemoptysis Lower respiratory tract inflammatory and immunologic conditions Alveolitis 1 Nasal congestion and inflammations Nasal congestion Nasal disorders NEC Epistaxis 2 Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion 1 Parenchymal lung disease 1 Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation 1 Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion 1 Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury 1 Acute respiratory distress syndrome	0
Tachypnoea Bronchospasm and obstruction Wheezing Coughing and associated symptoms Cough Haemoptysis Lower respiratory tract inflammatory and immunologic conditions Alveolitis 1 Nasal congestion and inflammations Nasal congestion Vasal disorders NEC Epistaxis 2 Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion 1 Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	0
Bronchospasm and obstruction Wheezing 2 Coughing and associated symptoms Cough 15 Haemoptysis 11 Lower respiratory tract inflammatory and immunologic conditions Alveolitis 11 Nasal congestion and inflammations Nasal congestion 2 Nasal disorders NEC Epistaxis 2 Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion 11 Parenchymal lung disease 11 Lung consolidation 11 Organising pneumonia 11 Pulmonary alveolar haemorrhage 11 Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation 11 Tonsillar hypertrophy 2 Pleural conditions NEC Pleural adhesion 11 Pneumothorax and pleural effusions NEC Pleural effusion 11 Pulmonary oedemas Acute lung injury 11 Acute respiratory distress syndrome 15	0
Wheezing Coughing and associated symptoms 15	0
Cough and associated symptoms Cough Haemoptysis Lower respiratory tract inflammatory and immunologic conditions Alveolitis Nasal congestion and inflammations Nasal congestion Nasal disorders NEC Epistaxis 2 Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion 1 Parenchymal lung disorders NEC Interstitial lung disease 1 Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion 1 Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	
Cough Haemoptysis Lower respiratory tract inflammatory and immunologic conditions Alveolitis Nasal congestion and inflammations Nasal congestion Nasal disorders NEC Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion 1 Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion 1 Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	0
Haemoptysis Lower respiratory tract inflammatory and immunologic conditions Alveolitis Nasal congestion and inflammations Nasal congestion Nasal disorders NEC Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion 1 Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion 1 Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	
Lower respiratory tract inflammatory and immunologic conditions Alveolitis Nasal congestion and inflammations Nasal congestion Nasal disorders NEC Epistaxis 2 Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion 1 Parenchymal lung disorders NEC Interstitial lung disease 1 Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion 1 Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	0
Alveolitis Nasal congestion and inflammations Nasal congestion Nasal disorders NEC Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion 1 Parenchymal lung disorders NEC Interstitial lung disease 1 Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion 1 Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	0
Nasal congestion and inflammations Nasal congestion Nasal disorders NEC Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	
Nasal congestion Nasal disorders NEC Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	0
Nasal disorders NEC Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	
Epistaxis Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	0
Paranasal sinus disorders (excl infections and neoplasms) Sinus congestion Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage 1 Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	
Sinus congestion Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage 1 Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	0
Sinus congestion Parenchymal lung disorders NEC Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage 1 Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome	
Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage 1 Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion 1 Pneumothorax and pleural effusions NEC Pleural effusion 1 Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome 1	0
Interstitial lung disease Lung consolidation Organising pneumonia Pulmonary alveolar haemorrhage 1 Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion 1 Pneumothorax and pleural effusions NEC Pleural effusion 1 Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome 1	
Lung consolidation 1 Organising pneumonia 1 Pulmonary alveolar haemorrhage 1 Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation 1 Tonsillar hypertrophy 2 Pleural conditions NEC Pleural adhesion 1 Pneumothorax and pleural effusions NEC Pleural effusion 1 Pulmonary oedemas Acute lung injury 1 Acute respiratory distress syndrome 1	0
Organising pneumonia Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome 1	0
Pulmonary alveolar haemorrhage Pharyngeal disorders (excl infections and neoplasms) Pharyngeal inflammation Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Information in the properties of t	0
Pharyngeal disorders (excl infections and neoplasms)Pharyngeal inflammation1Tonsillar hypertrophy2Pleural conditions NEC2Pleural adhesion1Pneumothorax and pleural effusions NEC1Pleural effusion1Pulmonary oedemas1Acute lung injury1Acute respiratory distress syndrome1	0
Pharyngeal inflammation 1 Tonsillar hypertrophy 2 Pleural conditions NEC Pleural adhesion 1 Pneumothorax and pleural effusions NEC Pleural effusion 1 Pulmonary oedemas Acute lung injury 1 Acute respiratory distress syndrome 1	
Tonsillar hypertrophy Pleural conditions NEC Pleural adhesion Pneumothorax and pleural effusions NEC Pleural effusion Pulmonary oedemas Acute lung injury Acute respiratory distress syndrome 2 Pleural effusion 1 Pulmonary oedemas 1	0
Pleural conditions NECPleural adhesion1Pneumothorax and pleural effusions NECPleural effusion1Pulmonary oedemas1Acute lung injury1Acute respiratory distress syndrome1	0
Pneumothorax and pleural effusions NECPleural effusion1Pulmonary oedemas1Acute lung injury1Acute respiratory distress syndrome1	
Pleural effusion 1 Pulmonary oedemas Acute lung injury 1 Acute respiratory distress syndrome 1	0
Pleural effusion 1 Pulmonary oedemas Acute lung injury 1 Acute respiratory distress syndrome 1	
Acute lung injury 1 Acute respiratory distress syndrome 1	0
Acute lung injury 1 Acute respiratory distress syndrome 1	
Acute respiratory distress syndrome 1	0
	0
	0
Pulmonary oedema 1	0
Pulmonary thrombotic and embolic conditions	
Pulmonary embolism 1	0
Respiratory failures (excl neonatal)	
Respiratory failure 1	0
Upper respiratory tract signs and symptoms	
Catarrh 1	0
Dry throat	0
Nasal discharge discolouration 1	0
Oropharyngeal discomfort	0
	0
Oropharyngeal pain 9 Rhinorrhoea 7	0
	0
Sneezing 2 Throat irritation 1	0
Throat initiation 1	0
Upper-airway cough syndrome	0
Respiratory disorders SOC TOTAL 75	0

Earliest Reaction Date: 15-Jan-2000	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	_ Fatal
Skin disorders		
Angioedemas		
Angioedema		1 0
Apocrine and eccrine gland disorders		
Cold sweat		1 0
Hyperhidrosis		2 0
Night sweats		1 0
Bullous conditions		
Blister		2 0
Dermal and epidermal conditions NEC		
Pain of skin		1 0
Papule		6 0
Skin discolouration		2 0
Skin tightness		1 0
Skin warm		8 0
Dermatitis and eczema		
Dermatitis allergic		6 o
Dermatitis diaper		2 0
Eczema		4 0
Seborrhoeic dermatitis		1 0
Dermatitis ascribed to specific agent		
Drug eruption		1 0
Erythemas		
Erythema	3	2 0
Pruritus NEC		
Pruritus		7 0
Purpura and related conditions		
Petechiae		2 0
Purpura		2 0
Rashes, eruptions and exanthems NEC		
Rash	12	el o
Rash erythematous		3 0
Rash macular		2 0
Rash maculo-papular		2 0
Rash morbilliform	3	4 0
Rash papular		6 0
Rash pruritic		2 0
Rash vesicular		1 0
Skin vasomotor conditions		
Livedo reticularis		1 0
Urticarias		
Urticaria		9 0
Skin disorders SOC TOTAL	27	-

Reaction Name	Total	Fatal
Vascular disorders		
Arterial infections and inflammations		
Kawasaki's disease	1	0
Peripheral vascular disorders NEC		
Cyanosis	1	0
Flushing	1	0
Site specific vascular disorders NEC		
Pallor	5	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Vascular disorders SOC TOTAL	9	0
TOTAL REACTIONS FOR DRUG	1392	4
TOTAL REPORTS	431	
TOTAL FATAL OUTCOME REPORTS		4