

Reaction MedDRA SOC Name	Reaction MedDRA HLGHT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Blood and lymphatic system disorders	Haematological disorders NEC	Haematological disorders	Methaemoglobinaemia	1	0
	Platelet disorders	Thrombocytopenias	Severe fever with thrombocytopenia syndrome	1	0
	Total			2	0
Cardiac disorders	Cardiac arrhythmias	Cardiac conduction disorders	Atrioventricular block	1	0
		Rate and rhythm disorders NEC	Bradycardia	1	0
			Tachycardia	5	0
		Supraventricular arrhythmias	Atrial fibrillation	2	0
			Supraventricular tachycardia	1	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	3	1
			Ventricular extrasystoles	2	0
			Ventricular fibrillation	1	0
	Ventricular tachycardia		1	0	
	Cardiac disorders, signs and symptoms NEC	Cardiac disorders NEC	Cardiovascular disorder	3	0
		Cardiac signs and symptoms NEC	Cyanosis	2	0
			Dizziness	24	0
			Dizziness postural	2	0
			Haemoptysis	6	0
			Palpitations	15	0
			Presyncope	2	0
		Dyspnoeas	Dyspnoea	68	0
	Dyspnoea exertional		1	0	
	Coronary artery disorders	Ischaemic coronary artery disorders	Angina pectoris	2	0
			Chest discomfort	27	0

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			Chest pain	32	0
	Endocardial disorders	Endocarditis NEC	Endocarditis noninfective	1	1
	Heart failures	Heart failure signs and symptoms	Peripheral swelling	1	0
		Heart failures NEC	Cardiac failure congestive	1	0
			Cardio-respiratory distress	1	0
		Left ventricular failures	Pulmonary congestion	2	0
			Pulmonary oedema	2	0
	Pericardial disorders	Pericardial disorders NEC	Pneumopericardium	1	0
	Total			210	2
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear infection	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Tinnitus	1	0
			Vertigo	3	0
	Total			5	0
Endocrine disorders	Glucose metabolism disorders (incl diabetes mellitus)	Hyperglycaemic conditions NEC	Glucose tolerance impaired	1	0
			Hyperglycaemia	1	0
	Thyroid gland disorders	Thyroid hypofunction disorders	Hypothyroidism	1	0
	Total			3	0
Eye disorders	Eye disorders NEC	Lacrimation disorders	Lacrimation increased	3	0
		Ocular disorders NEC	Eye pain	4	0
			Eye swelling	2	0
	Ocular infections, irritations and inflammations	Ocular infections, inflammations and associated manifestations	Eye irritation	1	0
			Eye pruritus	1	0
Vision disorders	Visual disorders NEC	Vision blurred	2	0	

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		Visual impairment and blindness (excl colour blindness)	Blindness transient	1	0	
	Total			14	0	
Gastrointestinal disorders	Abdominal hernias and other abdominal wall conditions	Diaphragmatic hernias	Hiatus hernia	1	0	
	Dental and gingival conditions	Dental pain and sensation disorders	Toothache	2	0	
		Gingival disorders, signs and symptoms NEC	Gingival discomfort	Gingival discomfort	1	0
			Gingival pain	Gingival pain	2	0
			Gingival recession	Gingival recession	2	0
			Gingival swelling	Gingival swelling	2	0
		Gingival haemorrhages	Gingival bleeding	4	0	
	Gastrointestinal conditions NEC	Gastrointestinal mucosal dystrophies and secretion disorders	Barrett's oesophagus	1	0	
	Gastrointestinal haemorrhages NEC	Intestinal haemorrhages	Rectal haemorrhage	1	0	
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	7	0	
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	Constipation	1	0
			Gastrooesophageal reflux disease	Gastrooesophageal reflux disease	4	0
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	3	0	
			Eructation	1	0	
		Faecal abnormalities NEC	Faeces discoloured	1	0	
		Flatulence, bloating and distension	Abdominal distension	Abdominal distension	3	0
			Flatulence	Flatulence	2	0
Gastrointestinal and abdominal pains (excl oral and throat)		Abdominal pain	Abdominal pain	3	0	

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			Abdominal pain upper	7	0
			Gastrointestinal pain	1	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	5	0
			Breath odour	1	0
			Dysphagia	1	0
			Hiccups	2	0
		Nausea and vomiting symptoms	Discoloured vomit	1	0
			Nausea	26	0
			Post-tussive vomiting	1	0
			Vomiting	7	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Cheilitis	1	0
			Oral disorder	2	0
		Oral soft tissue haemorrhages	Mouth haemorrhage	1	0
		Oral soft tissue infections	Pharyngitis	2	0
		Oral soft tissue signs and symptoms	Coating in mouth	1	0
			Hypoaesthesia oral	2	0
			Oral discomfort	6	0
			Oral mucosal blistering	1	0
			Oral mucosal erythema	1	0
			Oral pain	2	0
			Oropharyngeal discomfort	1	0
		Oropharyngeal pain	54	0	
		Paraesthesia oral	4	0	

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			Throat irritation	34	0	
		Oral soft tissue swelling and oedema	Lip swelling	4	0	
			Mouth swelling	2	0	
		Stomatitis and ulceration	Aphthous ulcer	1	0	
			Mouth ulceration	8	0	
			Stomatitis	3	0	
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	3	0	
				Dry throat	6	0
	Tongue conditions	Taste disorders	Dysgeusia	2	0	
				Taste disorder	2	0
			Tongue disorders	Glossitis	1	0
			Tongue signs and symptoms	Swollen tongue	4	0
				Tongue discomfort	3	0
				Tongue eruption	1	0
			Total	245	0	
General disorders and administration site conditions	Body temperature conditions	Febrile disorders	Pyrexia	8	0	
	General system disorders NEC	Asthenic conditions	Asthenia	1	0	
			Decreased activity	1	0	
			Fatigue	17	0	
			Lethargy	4	0	
			Malaise	14	0	
		Feelings and sensations NEC	Burning sensation	4	0	
			Chills	1	0	

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			Decreased appetite	1	0
			Feeling abnormal	3	0
			Feeling cold	1	0
			Feeling hot	2	0
			Feeling of body temperature change	1	0
			Increased appetite	1	0
			Peripheral coldness	1	0
		General signs and symptoms NEC	Balance disorder	1	0
			Cold sweat	1	0
			Condition aggravated	4	0
			Exercise tolerance decreased	1	0
			Hot flush	2	0
			Hyperhidrosis	2	0
			Illness	1	0
			Influenza like illness	4	0
			Irritability	1	0
			Pallor	1	0
			Peripheral swelling	1	0
			Swelling	2	0
			Swelling face	4	0
		Inflammmations	Inflammation	2	0
		Oedema NEC	Oedema	1	0
		Pain and discomfort NEC	Chest discomfort	27	0

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			Chest pain	32	0	
			Discomfort	2	0	
			Non-cardiac chest pain	5	0	
			Pain	2	0	
	Therapeutic and nontherapeutic effects (excl toxicity)	Interactions		Drug interaction	4	0
				Adverse drug reaction	3	0
		Therapeutic and nontherapeutic responses		Drug tolerance	1	0
				Therapeutic response unexpected	1	0
		Withdrawal and rebound effects		Medication overuse headache	1	0
				Tobacco withdrawal symptoms	1	0
	Tissue disorders NEC	Fibrosis NEC	Fibrosis	1	0	
	Total				168	0
	Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Hepatocellular damage and hepatitis NEC	Liver injury	1	0
Total				1	0	
Immune system disorders	Allergic conditions	Allergic conditions NEC	Allergic cough	1	0	
			Allergic respiratory disease	1	0	
			Asthma	12	0	
			Dermatitis allergic	2	0	
			Hypersensitivity	9	0	
			Hypersensitivity pneumonitis	3	0	
		Allergies to foods, food additives, drugs and other chemicals		Allergic reaction to excipient	1	0
				Reaction to excipient	12	0

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		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	2	0	
			Anaphylactic shock	1	0	
		Angioedemas	Angioedema	2	0	
			Lip swelling	4	0	
			Mouth swelling	2	0	
			Swelling face	4	0	
			Swollen tongue	4	0	
		Urticarias	Urticaria	2	0	
		Immune disorders NEC	Immune and associated conditions NEC	Acute respiratory distress syndrome	4	0
				Idiopathic pulmonary fibrosis	1	1
	Immune system disorder			1	0	
	Inflammation			2	0	
	Interstitial lung disease			2	0	
	Pulmonary alveolar haemorrhage			3	0	
	Immunodeficiency syndromes	Immunodeficiency disorders NEC	Immunodeficiency	1	0	
		Total			77	1
	Infections and infestations	Fungal infectious disorders	Pneumocystis infections	Pneumocystis jirovecii pneumonia	1	0
Infections - pathogen unspecified		Ear infections	Ear infection	1	0	
		Lower respiratory tract and lung infections	Bronchitis	3	0	
			Infectious pleural effusion	1	0	

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			Lower respiratory tract infection	2	0	
			Pneumonia	6	0	
		Upper respiratory tract infections	Croup infectious	1	0	
			Epiglottitis	1	0	
			Pharyngitis	2	0	
			Rhinitis	3	0	
			Sinusitis	6	0	
		Viral infectious disorders	Coronavirus infections	Severe acute respiratory syndrome	1	0
			Phleboviral infections	Severe fever with thrombocytopenia syndrome	1	0
		Total			29	0
		Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Maternal exposure during breast feeding	1
Maternal exposure during pregnancy	1				0	
Non-occupational environmental exposures	Environmental exposure			12	0	
Pathways and sources of exposure	Exposure via inhalation			3	0	
Poisoning and toxicity	Confirmed e-cigarette or vaping product use associated lung injury			1	0	
	Probable e-cigarette or vaping product use associated lung injury			2	0	
	Tobacco poisoning			1	0	
Injuries by physical agents	Thermal burns			Thermal burn	1	0

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	Injuries NEC	Abdominal and gastrointestinal injuries NEC	Liver injury	1	0
		Cerebral injuries NEC	Subarachnoid haemorrhage	1	0
		Chest and respiratory tract injuries NEC	Bronchial injury	1	0
		Nerve injuries NEC	Nerve injury	1	0
		Non-site specific injuries NEC	Accident	1	0
			Asphyxia	1	0
		Skin injuries NEC	Blister	2	0
	Medication errors and other product use errors and issues	Accidental exposures to product	Accidental exposure to product	3	0
		Medication errors, product use errors and issues NEC	Product use complaint	1	0
		Product administration errors and issues	Accidental overdose	1	0
			Expired product administered	1	0
			Incorrect route of product administration	2	0
	Procedural related injuries and complications NEC	Non-site specific procedural complications	Post-tussive vomiting	1	0
		Respiratory tract and thoracic cavity procedural complications	Pulmonary air leakage	1	0
		Skin procedural complications	Subcutaneous emphysema	2	0
	Total			42	0
	Investigations	Cardiac and vascular investigations (excl enzyme tests)	ECG investigations	Electrocardiogram T wave inversion	1
Heart rate and pulse investigations			Heart rate decreased	1	0
			Heart rate increased	1	0

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	Enzyme investigations NEC	Tissue enzyme analyses NEC	Blood alkaline phosphatase increased	1	0
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Gamma-glutamyltransferase increased	2	0
	Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature abnormal	1	0
			Breath sounds abnormal	1	0
			Weight decreased	1	0
	Respiratory and pulmonary investigations (excl blood gases)	Respiratory and pulmonary function diagnostic procedures	Pulmonary function test decreased	1	0
	Toxicology and therapeutic drug monitoring	Therapeutic drug monitoring analyses	Antipsychotic drug level increased	1	0
		Toxicology laboratory analyses	Breath alcohol test	1	0
	Total			13	0
Metabolism and nutrition disorders	Acid-base disorders	Mixed acid-base disorders	Acidosis	1	0
		Respiratory acidoses	Respiratory failure	2	0
	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	1	0
			Increased appetite	1	0
	Electrolyte and fluid balance conditions	Total fluid volume decreased	Dehydration	1	0
		Total fluid volume increased	Oedema	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Hyperglycaemic conditions NEC	Glucose tolerance impaired	1	0
			Hyperglycaemia	1	0
	Metabolism disorders NEC	Metabolic disorders NEC	Hypothyroidism	1	0
	Total			10	0

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Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Pain in jaw	1	0	
	Joint disorders	Joint related signs and symptoms	Arthralgia	5	0	
	Muscle disorders	Muscle pains	Muscle pains	Myalgia	3	0
			Muscle related signs and symptoms NEC	Chills	1	0
				Muscle contractions involuntary	1	0
				Muscle fatigue	1	0
				Muscle spasms	3	0
				Muscle tightness	2	0
			Muscle twitching	2	0	
	Muscle weakness conditions	Muscular weakness	1	0		
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Musculoskeletal and connective tissue conditions NEC	Musculoskeletal stiffness	1	0
			Musculoskeletal and connective tissue pain and discomfort	Back pain	1	0
				Musculoskeletal chest pain	2	0
				Neck pain	2	0
				Pain in extremity	1	0
	Tendon, ligament and cartilage disorders	Cartilage disorders	Costochondritis	1	0	
	Total			28	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm related morbidities	Oncologic complications and emergencies	Brain fog	1	0	
	Respiratory and mediastinal neoplasms malignant and unspecified	Laryngeal neoplasms malignant	Laryngeal cancer	1	0	
	Total			2	0	

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Nervous system disorders	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral infarction	1	0
			Spinal stroke	1	0
			Subarachnoid haemorrhage	1	0
	Cranial nerve disorders (excl neoplasms)	Auditory nerve disorders	Tinnitus	1	0
	Encephalopathies	Encephalopathies NEC	Posterior reversible encephalopathy syndrome	1	0
	Headaches	Headaches NEC	Cluster headache	1	0
			Headache	26	0
			Medication overuse headache	1	0
			Sinus headache	1	0
			Tension headache	2	0
			Thunderclap headache	1	0
		Migraine headaches	Migraine	5	0
	Mental impairment disorders	Memory loss (excl dementia)	Memory impairment	1	0
		Mental impairment (excl dementia and memory loss)	Disturbance in attention	1	0
			Mental fatigue	1	0
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	1	0
		Tremor (excl congenital)	Tremor	1	0
	Neurological disorders NEC	Coma states	Coma	1	0
		Coordination and balance disturbances	Balance disorder	1	0
		Cortical dysfunction NEC	Aphasia	1	0
Confusional state			5	0	

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		Disturbances in consciousness NEC	Depressed level of consciousness	1	0
			Lethargy	4	0
			Loss of consciousness	2	0
			Somnolence	1	0
		Nervous system disorders NEC	Nerve injury	1	0
		Neurological signs and symptoms NEC	Agitation	1	0
			Brain fog	1	0
			Dizziness	24	0
			Dizziness postural	2	0
			Head discomfort	1	0
			Presyncope	2	0
		Paraesthesias and dysaesthesias	Burning sensation	4	0
			Hypoaesthesia	2	0
			Hypoaesthesia oral	2	0
			Paraesthesia	3	0
			Paraesthesia oral	4	0
		Sensory abnormalities NEC	Dysgeusia	2	0
			Sensory disturbance	2	0
			Taste disorder	2	0
		Speech and language abnormalities	Aphonia	3	0
			Dysphonia	4	0
			Speech disorder	1	0
		Vertigos NEC	Vertigo	3	0

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	Neurological disorders of the eye	Neurologic visual problems NEC	Blindness transient	1	0
			Vision blurred	2	0
	Neuromuscular disorders	Neuromuscular disorders NEC	Muscle contractions involuntary	1	0
			Muscular weakness	1	0
	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Epilepsy	1	0
			Seizure	5	0
	Sleep disturbances (incl subtypes)	Disturbances in initiating and maintaining sleep	Insomnia	2	0
	Total			140	0
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortions spontaneous	Abortion spontaneous	1	0
	Neonatal and perinatal conditions	Neonatal respiratory disorders NEC	Pulmonary air leakage	1	0
	Pregnancy, labour, delivery and postpartum conditions	Exposures associated with pregnancy, delivery and lactation	Maternal exposure during breast feeding	1	0
			Maternal exposure during pregnancy	1	0
	Total			4	0
Product issues	Device issues	Device issues NEC	Device leakage	1	0
	Product quality, supply, distribution, manufacturing and quality system issues	Counterfeit, falsified and substandard products	Suspected counterfeit product	1	0
			Product label issues	Product expiration date issue	1
		Product label issue	Product label on wrong product	1	0
			Product physical issues	Liquid product physical issue	1
	Product colour issue	1	0		

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			Product leakage	1	0
			Product odour abnormal	4	0
			Product physical issue	6	0
			Product taste abnormal	14	0
		Product quality issues NEC	Product quality issue	1	0
			Product substitution issue	1	0
			Suspected product quality issue	2	0
	Total			36	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety disorders NEC	Anxiety disorder	1	0
		Anxiety symptoms	Agitation	1	0
			Anxiety	2	0
		Panic attacks and disorders	Panic attack	1	0
	Changes in physical activity	Decreased physical activity levels	Decreased activity	1	0
	Cognitive and attention disorders and disturbances	Cognitive and attention disorders and disturbances NEC	Brain fog	1	0
			Disturbance in attention	1	0
			Mental fatigue	1	0
		Specific cognitive ability disturbances	Aphasia	1	0
	Communication disorders and disturbances	Communications disorders	Aphonia	3	0
		Speech and language usage disturbances	Speech disorder	1	0
		Speech articulation and rhythm disturbances	Dysphonia	4	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	5	0
	Dementia and amnesic conditions	Amnesic symptoms	Memory impairment	1	0

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	Depressed mood disorders and disturbances	Depressive disorders	Depression	1	0
			Depression suicidal	1	0
		Mood alterations with depressive symptoms	Depressed mood	1	0
	Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Anger	1	0
			Euphoric mood	1	0
			Irritability	1	0
		Mood disorders NEC	Asthenia	1	0
			Laziness	1	0
			Lethargy	4	0
	Psychiatric disorders NEC	Substance related and addictive disorders	Dependence	1	0
			Nicotine dependence	2	0
			Tobacco abuse	1	0
			Tobacco withdrawal symptoms	1	0
Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	2	0	
	Dyssomnias	Somnolence	1	0	
Somatic symptom and related disorders	Somatic symptom disorders	Tension headache	2	0	
Total			46	0	
Renal and urinary disorders	Urinary tract signs and symptoms	Urinary tract signs and symptoms NEC	Renal pain	1	0
	Total			1	0
Reproductive system and breast disorders	Menopause related conditions	Menopausal effects NEC	Hot flush	2	0
	Total			2	0

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Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchial conditions NEC	Bronchial injury	1	0
		Bronchospasm and obstruction	Asthma	12	0
			Bronchial hyperreactivity	1	0
			Chronic obstructive pulmonary disease	1	0
			Wheezing	16	0
	Lower respiratory tract disorders (excl obstruction and infection)	Lower respiratory tract inflammatory and immunologic conditions	Alveolitis	1	0
			Diffuse alveolar damage	1	0
			Hypersensitivity pneumonitis	3	0
			Lower respiratory tract inflammation	1	0
			Pneumonia lipoid	3	1
			Pneumonitis	4	0
		Parenchymal lung disorders NEC	Confirmed e-cigarette or vaping product use associated lung injury	1	0
			Cystic lung disease	1	0
			Emphysema	1	0
			Idiopathic pulmonary fibrosis	1	1
			Interstitial lung disease	2	0
			Lung consolidation	4	0
			Organising pneumonia	2	0
			Probable e-cigarette or vaping product use associated lung injury	2	0
Pulmonary air leakage	1	0			

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			Pulmonary alveolar haemorrhage	3	0
			Pulmonary fibrosis	1	0
		Pulmonary oedemas	Acute lung injury	8	2
			Acute respiratory distress syndrome	4	0
			Pulmonary congestion	2	0
			Pulmonary oedema	2	0
	Pleural disorders	Pleural conditions NEC	Bronchopleural fistula	1	0
			Pleural adhesion	1	0
		Pleural infections and inflammations	Infectious pleural effusion	1	0
		Pneumothorax and pleural effusions NEC	Pleural effusion	4	0
			Pneumothorax	4	0
			Pneumothorax spontaneous	1	0
	Pulmonary vascular disorders	Pulmonary thrombotic and embolic conditions	Pulmonary embolism	1	0
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	68	0
			Dyspnoea exertional	1	0
			Respiration abnormal	1	0
			Respiratory arrest	1	0
			Respiratory distress	2	0
			Tachypnoea	3	0
		Conditions associated with abnormal gas exchange	Asphyxia	1	0
			Cyanosis	2	0

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			Hypoxia	4	0	
		Coughing and associated symptoms	Allergic cough	1	0	
			Cough	113	0	
			Haemoptysis	6	0	
			Post-tussive vomiting	1	0	
			Productive cough	10	0	
			Sputum increased	1	0	
			Respiratory failures (excl neonatal)	Cardio-respiratory distress	1	0
		Respiratory failure		2	0	
		Respiratory tract disorders NEC	Allergic respiratory disease	1	0	
			Lung disorder	2	0	
			Pulmonary mass	1	0	
			Respiratory disorder	3	0	
			Respiratory tract irritation	3	0	
	Respiratory tract infections	Fungal lower respiratory tract infections	Pneumocystis jirovecii pneumonia	1	0	
		Lower respiratory tract infections NEC	Bronchitis	3	0	
				Lower respiratory tract infection	2	0
				Pneumonia	6	0
		Upper respiratory tract infections NEC	Croup infectious	1	0	
				Epiglottitis	1	0
				Pharyngitis	2	0
				Rhinitis	3	0

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			Sinusitis	6	0
		Viral lower respiratory tract infections	Severe acute respiratory syndrome	1	0
	Respiratory tract neoplasms	Upper respiratory tract neoplasms	Laryngeal cancer	1	0
	Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Hiccups	2	0
			Lung opacity	5	0
			Pleuritic pain	2	0
			Pulmonary pain	10	0
			Rales	2	0
			Rhonchi	1	0
		Respiratory signs and symptoms NEC	Chest discomfort	27	0
			Chest pain	32	0
			Non-cardiac chest pain	5	0
		Upper respiratory tract signs and symptoms	Aphonia	3	0
			Catarrh	1	0
			Choking	3	0
			Dry throat	6	0
			Dysphonia	4	0
	Nasal discomfort		2	0	
	Oropharyngeal discomfort		1	0	
	Oropharyngeal pain		54	0	
	Rhinalgia		2	0	
	Rhinorrhoea		5	0	
	Sinus headache		1	0	

Reaction MedDRA SOC Name	Reaction MedDRA HLGHT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal	
			Sinus pain	1	0	
			Sneezing	4	0	
			Speech disorder	1	0	
			Throat irritation	34	0	
			Upper-airway cough syndrome	1	0	
	Thoracic disorders (excl lung and pleura)	Diaphragmatic disorders	Hiatus hernia	1	0	
		Mediastinal disorders	Pneumomediastinum	2	0	
		Thoracic musculoskeletal disorders	Musculoskeletal chest pain	2	0	
	Upper respiratory tract disorders (excl infections)	Laryngeal spasm, oedema and obstruction	Angioedema	2	0	
		Nasal congestion and inflammations	Nasal congestion	3	0	
		Nasal disorders NEC	Epistaxis	7	0	
			Nasal dryness	2	0	
		Paranasal sinus disorders (excl infections and neoplasms)	Sinus congestion	1	0	
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal disorder	1	0	
			Pharyngeal swelling	7	0	
	Total			584	4	
	Skin and subcutaneous tissue disorders	Angioedema and urticaria disorders	Angioedemas	Angioedema	2	0
				Lip swelling	4	0
				Mouth swelling	2	0
				Swelling face	4	0
Swollen tongue				4	0	
Urticarias		Urticaria	2	0		

Reaction MedDRA SOC Name	Reaction MedDRA HLGHT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal	
Epidermal and dermal conditions	Bullous conditions	Bullous conditions	Blister	2	0	
		Dermal and epidermal conditions NEC	Cheilitis	Cheilitis	1	0
			Dry skin	Dry skin	1	0
			Hypoaesthesia	Hypoaesthesia	2	0
			Pallor	Pallor	1	0
			Papule	Papule	1	0
			Paraesthesia	Paraesthesia	3	0
			Skin discolouration	Skin discolouration	1	0
			Skin sensitisation	Skin sensitisation	1	0
	Dermatitis and eczema	Dermatitis allergic	2	0		
	Erythemas	Erythema	3	0		
	Pruritus NEC	Pruritus	8	0		
	Rashes, eruptions and exanthems NEC	Rash	Rash	12	0	
		Rash papular	Rash papular	1	0	
	Skin injuries and mechanical dermatoses	Thermal burn	Thermal burn	1	0	
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Skin mass	Skin mass	1	0
			Subcutaneous emphysema	Subcutaneous emphysema	2	0
Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	Cold sweat	1	0	
		Hyperhidrosis	Hyperhidrosis	2	0	
	Pilar disorders NEC	Hair texture abnormal	Hair texture abnormal	1	0	
Skin vascular abnormalities	Skin vascular conditions NEC	Cyanosis	Cyanosis	2	0	
		Peripheral coldness	Peripheral coldness	1	0	
Total				68	0	

Reaction MedDRA SOC Name	Reaction MedDRA HLGHT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Social circumstances	Lifestyle issues	Tobacco use	Electronic cigarette user	1	0
	Total			1	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Cerebrovascular and spinal necrosis and vascular insufficiency	Cerebral infarction	1	0
		Coronary necrosis and vascular insufficiency	Angina pectoris	2	0
		Non-site specific necrosis and vascular insufficiency NEC	Vasospasm	1	0
		Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	1	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Anaphylactic shock	1	0
			Dizziness	24	0
			Dizziness postural	2	0
			Presyncope	2	0
		Vascular hypotensive disorders	Anaphylactic reaction	2	0
			Hypotension	2	0
	Embolism and thrombosis	Pulmonary embolism and thrombosis	Pulmonary embolism	1	0
	Vascular disorders NEC	Cerebrovascular and spinal vascular disorders NEC	Migraine	5	0
			Spinal stroke	1	0
		Non-site specific vascular disorders NEC	Acute respiratory distress syndrome	4	0
			Cardiovascular disorder	3	0
		Peripheral vascular disorders NEC	Cyanosis	2	0
			Hot flush	2	0
		Pulmonary vascular disorders NEC	Pulmonary congestion	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Site specific vascular disorders NEC	Pallor	1	0
	Vascular haemorrhagic disorders	Gastrointestinal haemorrhages	Gingival bleeding	4	0
			Mouth haemorrhage	1	0
			Rectal haemorrhage	1	0
		Haemorrhages NEC	Epistaxis	7	0
			Haemoptysis	6	0
			Pulmonary alveolar haemorrhage	3	0
			Severe fever with thrombocytopenia syndrome	1	0
		Nervous system haemorrhagic disorders	Subarachnoid haemorrhage	1	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	3	0
	Total			86	0
Total				1,817	7