

## COVID-19 vaccine Moderna analysis print

Report Run Date: 20-May-2021  
Data Lock Date: 19-May-2021 18:30:09

All UK spontaneous reports received up to and including 19/05/2021 for COVID-19 vaccine Moderna.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine Moderna analysis print

Report Run Date: 20-May-2021

Data Lock Date: 19-May-2021 18:30:09

Earliest Reaction Date: 15-Oct-1958

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymph node pain	14	0
Lymphadenitis	2	0
Lymphadenopathy	83	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	2	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>103</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	22	0
<i>Ischaemic coronary artery disorders</i>		
Myocardial infarction	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Bradycardia	1	0
Extrasystoles	1	0
Tachycardia	7	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>35</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear congestion	1	0
Ear pain	9	0
<i>Hearing losses</i>		
Deafness	2	0
Deafness unilateral	2	0
Hypoacusis	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	2	0
Tinnitus	39	0
Vertigo	15	0
<b>Ear disorders SOC TOTAL</b>	<b>72</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	1	0
<i><b>Cataract conditions</b></i>		
Cataract	1	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	1	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	2	0
Lacrimation increased	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	13	0
Eye swelling	6	0
Periorbital swelling	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	1	0
Eye irritation	2	0
Eye pruritus	2	0
Ocular hyperaemia	4	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	1	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	1	0
Photophobia	4	0
<i><b>Visual disorders NEC</b></i>		
Vision blurred	22	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	1	0
Visual impairment	1	0
<b>Eye disorders SOC TOTAL</b>	<b>65</b>	<b>0</b>

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<b>Gastrointestinal disorders</b>		
<i><b>Anal and rectal signs and symptoms</b></i>		
Anal pruritus	1	0
<i><b>Colitis (excl infective)</b></i>		
Colitis ulcerative	1	0
Crohn's disease	2	0
<i><b>Dental pulp disorders</b></i>		
Dental pulp disorder	1	0
<i><b>Diarrhoea (excl infective)</b></i>		
Diarrhoea	58	0
<i><b>Dyspeptic signs and symptoms</b></i>		
Dyspepsia	4	0
Epigastric discomfort	1	0
<i><b>Faecal abnormalities NEC</b></i>		
Faeces discoloured	1	0
<i><b>Flatulence, bloating and distension</b></i>		
Abdominal distension	2	0
Flatulence	1	0
<i><b>Gastric ulcers and perforation</b></i>		
Gastritis erosive	1	0
<i><b>Gastrointestinal and abdominal pains (excl oral and throat)</b></i>		
Abdominal pain	12	0
Abdominal pain upper	28	0
Gastrointestinal pain	3	0
<i><b>Gastrointestinal atonic and hypomotility disorders NEC</b></i>		
Constipation	3	0
Gastrooesophageal reflux disease	3	0
<i><b>Gastrointestinal disorders NEC</b></i>		
Food poisoning	1	0
<i><b>Gastrointestinal signs and symptoms NEC</b></i>		
Abdominal discomfort	4	0
Breath odour	1	0
Dysphagia	1	0
<i><b>Gingival disorders, signs and symptoms NEC</b></i>		
Gingival swelling	1	0
<i><b>Gingival haemorrhages</b></i>		
Gingival bleeding	1	0
<i><b>Nausea and vomiting symptoms</b></i>		
Discoloured vomit	1	0
Nausea	154	0
Vomiting	46	0
<i><b>Non-site specific gastrointestinal haemorrhages</b></i>		
Haematemesis	1	0
Haematochezia	1	0
<i><b>Oral dryness and saliva altered</b></i>		
Dry mouth	8	0
Lip dry	4	0
Saliva altered	1	0
Salivary hypersecretion	1	0
<i><b>Oral soft tissue haemorrhages</b></i>		
Oral blood blister	2	0
<i><b>Oral soft tissue signs and symptoms</b></i>		
Coating in mouth	1	0
Hypoaesthesia oral	9	0

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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Lip pain	1	0
Oral discomfort	1	0
Oral mucosal eruption	1	0
Paraesthesia oral	21	0
<b>Oral soft tissue swelling and oedema</b>		
Lip swelling	10	0
Mouth swelling	4	0
<b>Stomatitis and ulceration</b>		
Apthous ulcer	1	0
Mouth ulceration	5	0
Stomatitis	1	0
<b>Tongue disorders</b>		
Glossitis	1	0
Tongue disorder	1	0
Tongue ulceration	1	0
<b>Tongue signs and symptoms</b>		
Glossodynia	2	0
Swollen tongue	9	0
Tongue dry	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>420</b>	<b>0</b>

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<b>General disorders</b>		
<i><b>Adverse effect absent</b></i>		
No adverse event	1	0
<i><b>Application and instillation site reactions</b></i>		
Application site burn	1	0
Application site pruritus	2	0
Application site warmth	1	0
<i><b>Asthenic conditions</b></i>		
Asthenia	14	0
Fatigue	271	0
Malaise	46	0
<i><b>Death and sudden death</b></i>		
Death	2	2
<i><b>Febrile disorders</b></i>		
Pyrexia	145	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	107	0
Feeling abnormal	24	0
Feeling cold	16	0
Feeling drunk	2	0
Feeling hot	21	0
Feeling jittery	1	0
Feeling of body temperature change	6	0
Hunger	1	0
Sensation of foreign body	1	0
Thirst	8	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	2	0
Crying	4	0
Exercise tolerance decreased	1	0
Illness	14	0
Induration	2	0
Influenza like illness	19	0
Local reaction	2	0
Peripheral swelling	194	0
Screaming	1	0
Swelling	97	0
Swelling face	12	0
<i><b>Inflammations</b></i>		
Inflammation	13	0
Soft tissue inflammation	1	0
<i><b>Infusion site reactions</b></i>		
Infusion site mass	1	0
Infusion site pain	3	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
<i><b>Injection site reactions</b></i>		
Injection site bruising	1	0
Injection site erythema	17	0
Injection site inflammation	2	0
Injection site joint erythema	1	0
Injection site mass	16	0
Injection site pain	42	0
Injection site pruritus	14	0



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<b>General disorders</b> General disorders cont'd		
Injection site rash	27	0
Injection site reaction	3	0
Injection site swelling	3	0
Injection site urticaria	12	0
Injection site warmth	11	0
<b>Mass conditions NEC</b>		
Cyst	1	0
Mass	3	0
Nodule	1	0
<b>Oedema NEC</b>		
Localised oedema	1	0
Oedema	1	0
<b>Pain and discomfort NEC</b>		
Axillary pain	42	0
Chest discomfort	6	0
Chest pain	20	0
Discomfort	12	0
Pain	94	0
Tenderness	16	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	10	0
Drug ineffective	1	0
<b>Vaccination site reactions</b>		
Vaccination site bruising	2	0
Vaccination site discomfort	1	0
Vaccination site erythema	49	0
Vaccination site induration	5	0
Vaccination site inflammation	3	0
Vaccination site mass	6	0
Vaccination site movement impairment	1	0
Vaccination site oedema	1	0
Vaccination site pain	35	0
Vaccination site papule	1	0
Vaccination site pruritus	15	0
Vaccination site rash	17	0
Vaccination site swelling	22	0
Vaccination site urticaria	1	0
Vaccination site warmth	19	0
<b>Withdrawal and rebound effects</b>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	1	0
<b>General disorders SOC TOTAL</b>	<b>1575</b>	<b>2</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Hepatic disorders</b>		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	1	0
Hypersensitivity	28	0
Infusion related hypersensitivity reaction	1	0
Type IV hypersensitivity reaction	3	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	1	0
Drug hypersensitivity	2	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	9	0
Anaphylactic shock	1	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Bacille Calmette-Guerin scar reactivation	3	0
<b>Immune system disorders SOC TOTAL</b>	<b>50</b>	<b>0</b>

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<b>Infections</b>		
<b><i>Bacterial infections NEC</i></b>		
Cellulitis	9	0
<b><i>Breast infections</i></b>		
Breast abscess	1	0
<b><i>Candida infections</i></b>		
Candida infection	1	0
Vulvovaginal candidiasis	3	0
<b><i>Coronavirus infections</i></b>		
COVID-19	2	0
<b><i>Coxiella infections</i></b>		
Q fever	1	0
<b><i>Ear infections</i></b>		
Labyrinthitis	2	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	3	0
<b><i>Fungal infections NEC</i></b>		
Fungal skin infection	1	0
<b><i>Herpes viral infections</i></b>		
Herpes zoster	11	0
Oral herpes	5	0
<b><i>Infections NEC</i></b>		
Abscess limb	1	0
Infection	11	0
Localised infection	2	0
Respiratory tract infection	1	0
Vaccination site infection	1	0
Vestibulitis	1	0
<b><i>Infectious disorders carrier</i></b>		
SARS-CoV-2 carrier	1	0
<b><i>Infectious transmissions</i></b>		
Secondary transmission	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	11	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Lower respiratory tract infection	3	0
Pneumonia	3	0
<b><i>Rabies viral infections</i></b>		
Rabies	1	1
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Pustule	3	0
Skin infection	2	0
<b><i>Tinea infections</i></b>		
Body tinea	1	0
<b><i>Tuberculous infections</i></b>		
Disseminated Bacillus Calmette-Guerin infection	1	0
<b><i>Upper respiratory tract infections</i></b>		
Nasopharyngitis	16	0
Sinusitis	1	0
<b><i>Urinary tract infections</i></b>		
Cystitis	1	0
Urinary tract infection	1	0

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Sweating fever	2	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>107</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Conditions caused by cold</i>		
Chillblains	3	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	11	0
Maternal exposure during pregnancy	12	0
Paternal exposure during pregnancy	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	1	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	1	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Procedural pain	1	0
<i>Product administration errors and issues</i>		
Incorrect dose administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
Limb injury	1	0
<i>Skin injuries NEC</i>		
Contusion	12	0
Subcutaneous haematoma	1	0
<i>Stoma complications</i>		
Stoma site oedema	1	0
<i>Thermal burns</i>		
Thermal burn	3	0
<b>Injuries SOC TOTAL</b>	<b>56</b>	<b>0</b>

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<b>Investigations</b>		
<i><b>Adrenal medulla tests</b></i>		
Norepinephrine increased	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate	6	0
Heart rate abnormal	1	0
Heart rate increased	6	0
Heart rate irregular	1	0
<i><b>Liver function analyses</b></i>		
Liver function test abnormal	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	3	0
Body temperature decreased	1	0
Body temperature increased	3	0
Lymph node palpable	1	0
Respiratory rate increased	2	0
Skin temperature	2	0
Weight decreased	2	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output	2	0
<i><b>Urinary tract imaging procedures</b></i>		
Bladder scan	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure increased	1	0
Blood pressure measurement	2	0
<i><b>Virus identification and serology</b></i>		
SARS-CoV-2 antibody test	1	0
<b>Investigations SOC TOTAL</b>	<b>38</b>	<b>0</b>

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<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	8	0
Increased appetite	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	3	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	4	0
<b>Metabolic disorders SOC TOTAL</b>	<b>19</b>	<b>0</b>



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<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	3	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	4	0
Pain in jaw	3	0
Spinal pain	2	0
<i><b>Connective tissue disorders NEC</b></i>		
Reynold's syndrome	1	0
<i><b>Joint related disorders NEC</b></i>		
Periarthritis	1	0
Rotator cuff syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	81	0
Joint noise	1	0
Joint stiffness	4	0
Joint swelling	5	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	1	0
Myalgia	101	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	3	0
Muscle haemorrhage	1	0
Muscle spasms	17	0
Muscle swelling	1	0
Muscle tightness	4	0
Muscle twitching	3	0
<i><b>Muscle tone abnormalities</b></i>		
Nuchal rigidity	1	0
Trismus	2	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	5	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Musculoskeletal stiffness	28	0
<i><b>Musculoskeletal and connective tissue infections and inflammations NEC</b></i>		
Dupuytren's contracture	1	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	14	0
Flank pain	1	0
Limb discomfort	32	0
Musculoskeletal discomfort	1	0
Neck pain	14	0
Pain in extremity	259	0
<i><b>Myopathies</b></i>		
Rhabdomyolysis	1	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	2	0
Groin pain	1	0
Soft tissue swelling	1	0
<i><b>Tendon disorders</b></i>		
Trigger finger	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>601</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Nervous system disorders</b>		
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Cerebral haemorrhage	2	1
Cerebrovascular accident	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	1	0
<b><i>Coordination and balance disturbances</i></b>		
Dysstasia	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Lethargy	28	0
Loss of consciousness	7	0
Somnolence	17	0
Syncope	35	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Clumsiness	1	0
Movement disorder	1	0
<b><i>Facial cranial nerve disorders</i></b>		
Bell's palsy	4	0
Facial paralysis	5	0
<b><i>Headaches NEC</i></b>		
Cluster headache	5	0
Headache	265	0
Sinus headache	2	0
Tension headache	3	0
<b><i>Memory loss (excl dementia)</i></b>		
Memory impairment	1	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	1	0
Disturbance in attention	8	0
<b><i>Migraine headaches</i></b>		
Migraine	19	0
Migraine with aura	2	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Dizziness	167	0
Dizziness postural	8	0
Head discomfort	2	0
Neurological symptom	1	0
Presyncope	9	0
Unresponsive to stimuli	1	0
<b><i>Olfactory nerve disorders</i></b>		
Parosmia	2	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	12	0
Hyperaesthesia	2	0
Hypoaesthesia	45	0
Paraesthesia	75	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Hemiplegia	1	0
Monoparesis	1	0
Paralysis	2	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Febrile convulsion	1	0

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine Moderna analysis print

Report Run Date: 20-May-2021  
 Earliest Reaction Date: 15-Oct-1958

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Seizure	3	0
Status epilepticus	5	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	2	0
Dysgeusia	32	0
Electric shock sensation	1	0
Neuralgia	3	0
Post herpetic neuralgia	1	0
Restless legs syndrome	2	0
Sensory disturbance	2	0
Taste disorder	5	0
<b><i>Sleep disturbances NEC</i></b>		
Sleep deficit	1	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	2	0
Incoherent	2	0
Slow speech	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	1	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	15	0
<b>Nervous system disorders SOC TOTAL</b>	<b>818</b>	<b>1</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
<i>Stillbirth and foetal death</i>		
Stillbirth	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>6</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device issues NEC</i>		
Device leakage	1	0
<b>null SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	1	0
Anxiety	8	0
Nervousness	4	0
Stress	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Distractibility	1	0
Mental fatigue	2	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	8	0
Disorientation	3	0
<b><i>Depressive disorders</i></b>		
Depression	4	0
<b><i>Dissociative states</i></b>		
Dissociation	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	11	0
Terminal insomnia	1	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	2	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	4	0
Emotional disorder	3	0
Emotional distress	2	0
Euphoric mood	1	0
Irritability	3	0
Mood altered	2	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	5	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	1	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	4	0
<b><i>Mood disorders NEC</i></b>		
Apathy	2	0
Listless	1	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	1	0
Panic reaction	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	4	0
Nightmare	6	0
Somnambulism	1	0
<b><i>Perception disturbances NEC</i></b>		
Autoscopy	1	0
<b><i>Sexual desire disorders</i></b>		
Libido decreased	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	2	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>97</b>	<b>0</b>



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Dysuria	1	0
Pollakiuria	2	0
<i>Urinary abnormalities</i>		
Chromaturia	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	3	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	1	0
<i><b>Breast disorders NEC</b></i>		
Fibrocystic breast disease	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast pain	4	0
Nipple swelling	1	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	10	0
Intermenstrual bleeding	10	0
Menstrual disorder	11	0
Menstruation irregular	23	0
Premenstrual syndrome	2	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	4	0
Hypomenorrhoea	1	0
Menstruation delayed	4	0
Oligomenorrhoea	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	34	0
Polymenorrhoea	1	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Polycystic ovaries	1	0
<i><b>Penile disorders NEC (excl erection and ejaculation)</b></i>		
Penis disorder	1	0
<i><b>Prostate and seminal vesicles infections and inflammations</b></i>		
Prostatitis	1	0
<i><b>Prostatic signs, symptoms and disorders NEC</b></i>		
Prostatic pain	1	0
<i><b>Reproductive tract disorders NEC (excl neoplasms)</b></i>		
Genital haemorrhage	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	2	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular swelling	1	0
<i><b>Uterine tone disorders</b></i>		
Uterine spasm	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	18	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vulvovaginal discomfort	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>137</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	29	0
Hypopnoea	1	0
Respiratory distress	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	2	0
Wheezing	7	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	18	0
Haemoptysis	1	0
Productive cough	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	5	0
Pulmonary haemorrhage	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	3	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	14	0
Nasal oedema	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	6	0
Tonsillar hypertrophy	1	0
<i><b>Pulmonary hypertension</b></i>		
Pulmonary hypertension	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary oedema	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Dry throat	1	0
Nasal discomfort	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	28	0
Rhinorrhoea	8	0
Sinus pain	5	0
Sneezing	1	0
Throat irritation	5	0
Throat tightness	2	0
Upper-airway cough syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>150</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	1	0
<b><i>Alopecias</i></b>		
Alopecia	4	0
<b><i>Angioedemas</i></b>		
Angioedema	4	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	8	0
Hyperhidrosis	14	0
Miliaria	4	0
Night sweats	4	0
<b><i>Bullous conditions</i></b>		
Blister	8	0
Erythema multiforme	2	0
Stevens-Johnson syndrome	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	7	0
Pain of skin	5	0
Papule	3	0
Sensitive skin	2	0
Skin burning sensation	8	0
Skin induration	2	0
Skin lesion	3	0
Skin reaction	16	0
Skin sensitisation	1	0
Skin swelling	3	0
Skin warm	21	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	1	0
Dermatitis allergic	15	0
Dermatitis atopic	2	0
Dyshidrotic eczema	1	0
Eczema	5	0
Skin irritation	5	0
<b><i>Erythemas</i></b>		
Erythema	133	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	1	0
<b><i>Hyperpigmentation disorders</i></b>		
Skin hyperpigmentation	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Onychoclasia	1	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	1	0
<b><i>Photosensitivity and photodermatitis conditions</i></b>		
Photosensitivity reaction	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	313	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	1	0
Rash	253	0

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Skin disorders</b> Skin disorders cont'd		
Rash erythematous	121	0
Rash macular	11	0
Rash papular	17	0
Rash pruritic	78	0
<b>Rosaceas</b>		
Rosacea	1	0
<b>Skin cysts and polyps</b>		
Dermal cyst	1	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	1	0
<b>Urticarias</b>		
Urticaria	44	0
<b>Skin disorders SOC TOTAL</b>	<b>1130</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menopause	2	0
<i>Disability issues</i>		
Immobile	1	0
<i>Employment issues</i>		
Retirement	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	1	0
<b>Social circumstances SOC TOTAL</b>	<b>5</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Surgical &amp; medical procedures</b>		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Therapeutic procedures NEC</i>		
Injection	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Haemorrhages NEC</b></i>		
Bloody discharge	1	0
Haemorrhage	9	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Embolism	1	0
Thrombosis	3	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Blue toe syndrome	1	0
Deep vein thrombosis	1	0
Venous thrombosis limb	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Flushing	5	0
Hot flush	13	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	4	0
Raynaud's phenomenon	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	5	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	11	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	10	0
<i><b>Vasculitides NEC</b></i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>67</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>5567</b>	<b>4</b>
<b>TOTAL REPORTS</b>	<b>1972</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>4</b>