

## **Covid-19 Moderna Vaccine Analysis Print**

All UK suspected spontaneous ADR reports for Covid-19 Moderna vaccines received from Scotland up to 10.11.2021

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 that it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be a factor 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 Moderna Vaccine Analysis Print (VAP)

Report Run Date: 22-Nov-2021

Data Lock Date: 21-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Iron deficiency anaemia	1	0
<i><b>Anaemias NEC</b></i>		
Anaemia	1	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	2	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	19	0
Lymphadenitis	1	0
Lymphadenopathy	106	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	2	0
<b>Blood disorders SOC TOTAL</b>	<b>133</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	59	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	4	0
<i>Noninfectious myocarditis</i>		
Myocarditis	9	0
<i>Noninfectious pericarditis</i>		
Pericarditis	5	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	4	0
Cardiac flutter	6	0
Extrasystoles	2	0
Tachycardia	11	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Sinus arrhythmia	1	0
Supraventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>103</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear congestion	2	0
Ear discomfort	1	0
Ear disorder	2	0
Ear pain	12	0
<i>Hearing losses</i>		
Deafness	2	0
Hypoacusis	6	0
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	16	0
Vertigo	14	0
Vertigo positional	1	0
<b>Ear disorders SOC TOTAL</b>	<b>59</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
Ovulation delayed	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous floaters	1	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	3	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	1	0
Lacrimation increased	2	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	10	0
Eye swelling	5	0
Ocular discomfort	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Ocular hyperaemia	3	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	1	0
Photophobia	6	0
<i><b>Pupil disorders</b></i>		
Mydriasis	2	0
<i><b>Retinal bleeding and vascular disorders (excl retinopathy)</b></i>		
Retinal vein occlusion	1	0
<i><b>Scleral infections, irritations and inflammations</b></i>		
Episcleritis	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	1	0
Photopsia	1	0
Vision blurred	11	0
<i><b>Visual field disorders</b></i>		
Visual field defect	1	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	1	0
Blindness transient	1	0
Visual impairment	3	0
<b>Eye disorders SOC TOTAL</b>	<b>56</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	1	0
Crohn's disease	1	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	1	0
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	52	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	11	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	5	0
Flatulence	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	14	0
Abdominal pain lower	3	0
Abdominal pain upper	38	0
Abdominal tenderness	1	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrooesophageal reflux disease	3	0
<i>Gastrointestinal disorders NEC</i>		
Stomach mass	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	8	0
Breath odour	1	0
Dysphagia	3	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival swelling	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	242	0
Vomiting	83	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
Upper gastrointestinal haemorrhage	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	5	0
Lip dry	1	0
Salivary hypersecretion	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Oral soft tissue disorders NEC</i></b>		
Cheilitis	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	3	0
Oral pain	4	0
Paraesthesia oral	5	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	11	0
Mouth swelling	2	0
<b><i>Rectal inflammations NEC</i></b>		
Proctitis	1	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	1	0
Mouth ulceration	7	0
Stomatitis	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	4	0
Swollen tongue	5	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>538</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site warmth	1	0
<i>Asthenic conditions</i>		
Asthenia	28	0
Fatigue	290	0
Malaise	41	0
<i>Death and sudden death</i>		
Death	2	2
<i>Febrile disorders</i>		
Pyrexia	344	0
<i>Feelings and sensations NEC</i>		
Chills	175	0
Feeling abnormal	25	0
Feeling cold	10	0
Feeling hot	24	0
Feeling jittery	1	0
Feeling of body temperature change	6	0
Hunger	1	0
Sensation of blood flow	1	0
Sensation of foreign body	2	0
Temperature intolerance	2	0
Thirst	3	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Crying	2	0
Discharge	1	0
Effusion	1	0
Energy increased	1	0
Illness	24	0
Influenza like illness	25	0
Local reaction	1	0
Peripheral swelling	144	0
Swelling	76	0
Swelling face	8	0
<i>Implant and catheter site reactions</i>		
Implant site warmth	1	0
<i>Inflammations</i>		
Inflammation	10	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site erythema	12	0
Injection site haemorrhage	1	0
Injection site hypoaesthesia	1	0
Injection site inflammation	2	0
Injection site joint erythema	1	0
Injection site mass	17	0
Injection site pain	46	0
Injection site pruritus	15	0
Injection site rash	17	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site reaction	3	0
Injection site swelling	6	0
Injection site urticaria	2	0
Injection site warmth	7	0
<b>Mass conditions NEC</b>		
Mass	1	0
Nodule	1	0
<b>Oedema NEC</b>		
Oedema	2	0
<b>Pain and discomfort NEC</b>		
Axillary pain	38	0
Chest discomfort	31	0
Chest pain	63	0
Discomfort	12	0
Facial pain	2	0
Pain	144	0
Tenderness	15	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	2	0
Drug ineffective	1	0
<b>Vaccination site reactions</b>		
Shoulder injury related to vaccine administration	1	0
Vaccination site erythema	23	0
Vaccination site hypoaesthesia	2	0
Vaccination site induration	1	0
Vaccination site inflammation	1	0
Vaccination site irritation	1	0
Vaccination site mass	4	0
Vaccination site pain	19	0
Vaccination site pruritus	3	0
Vaccination site rash	11	0
Vaccination site scar	1	0
Vaccination site swelling	15	0
Vaccination site urticaria	1	0
Vaccination site warmth	10	0
<b>General disorders SOC TOTAL</b>	<b>1790</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Bile duct infections and inflammations</i>		
Biliary colic	2	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	1	0
Hypersensitivity	32	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	1	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	1	0
Anaphylactic shock	2	0
<i><b>Atopic disorders</b></i>		
Seasonal allergy	2	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>46</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	9	0
Injection site cellulitis	1	0
<i><b>Breast infections</b></i>		
Breast abscess	1	0
<i><b>Candida infections</b></i>		
Candida infection	1	0
Vulvovaginal candidiasis	1	0
<i><b>Coronavirus infections</b></i>		
COVID-19	9	0
<i><b>Dental and oral soft tissue infections</b></i>		
Gingivitis	1	0
<i><b>Enteroviral infections NEC</b></i>		
Hand-foot-and-mouth disease	1	0
<i><b>Epstein-Barr viral infections</b></i>		
Infectious mononucleosis	1	0
<i><b>Fungal infections NEC</b></i>		
Fungal infection	1	0
Fungal skin infection	1	0
<i><b>Herpes viral infections</b></i>		
Genital herpes	2	0
Herpes simplex	1	0
Herpes zoster	5	0
Ophthalmic herpes simplex	1	0
Oral herpes	11	0
<i><b>Infections NEC</b></i>		
Infection	8	0
Localised infection	1	0
Vaccination site infection	1	0
<i><b>Infectious disorders carrier</b></i>		
SARS-CoV-2 carrier	1	0
<i><b>Influenza viral infections</b></i>		
Influenza	27	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
Lower respiratory tract infection	2	1
Pneumonia	1	0
<i><b>Nematode infections</b></i>		
Enterobiasis	1	0
<i><b>Rubella viral infections</b></i>		
Rubella	1	0
<i><b>Skin structures and soft tissue infections</b></i>		
Impetigo	1	0
Skin infection	2	0
<i><b>Staphylococcal infections</b></i>		
Furuncle	1	0
<i><b>Tinea infections</b></i>		
Body tinea	1	0
<i><b>Tuberculous infections</b></i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	14	0
Pharyngitis	1	0

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Tonsillitis	2	0
<i>Urinary tract infections</i>		
Urinary tract infection	2	0
<i>Vascular infections</i>		
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Sweating fever	3	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>121</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Anaesthetic and allied procedural complications</i></b>		
Anaesthetic complication	1	0
<b><i>Cerebral injuries NEC</i></b>		
Concussion	2	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	51	0
Maternal exposure during pregnancy	23	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat oedema	1	0
<b><i>Limb fractures and dislocations</i></b>		
Clavicle fracture	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Muscle injury	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Fall	1	0
<b><i>Overdoses NEC</i></b>		
Overdose	2	0
<b><i>Product administration errors and issues</i></b>		
Expired product administered	1	0
<b><i>Radiation injuries</i></b>		
Sunburn	1	0
<b><i>Site specific injuries NEC</i></b>		
Head injury	1	0
Limb injury	5	0
<b><i>Skin injuries NEC</i></b>		
Contusion	17	0
Scar	1	0
Scratch	1	0
<b><i>Thermal burns</i></b>		
Thermal burn	1	0
<b>Injuries SOC TOTAL</b>	<b>114</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal medulla tests</i></b>		
Norepinephrine increased	1	0
<b><i>Bacteria identification and serology (excl mycobacteria)</i></b>		
Campylobacter test positive	1	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	1	0
<b><i>Gastrointestinal and abdominal imaging procedures</i></b>		
X-ray with contrast upper gastrointestinal tract	1	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	16	0
Heart rate abnormal	1	0
Heart rate decreased	1	0
Heart rate increased	22	0
Heart rate irregular	4	0
Heart rate variability decreased	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood potassium decreased	1	0
Serum ferritin increased	1	0
<b><i>Musculoskeletal and soft tissue imaging procedures</i></b>		
Bone scan	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	1	0
Body temperature fluctuation	2	0
Body temperature increased	5	0
Respiratory rate	1	0
Respiratory rate decreased	1	0
Skin temperature	1	0
Temperature difference of extremities	1	0
Weight decreased	1	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	1	0
<b><i>Therapeutic drug monitoring analyses</i></b>		
Analgesic drug level	1	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood lactate dehydrogenase increased	1	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure increased	2	0
<b><i>Virus identification and serology</i></b>		
SARS-CoV-2 test negative	2	0
<b><i>Vitamin analyses</i></b>		
Blood folate decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>73</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	26	0
Food refusal	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	1	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	4	0
<b>Metabolic disorders SOC TOTAL</b>	<b>33</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	4	0
Arthropathy	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	5	0
Pain in jaw	4	0
<i><b>Bursal disorders</b></i>		
Bursitis	3	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	1	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	1	0
<i><b>Joint related disorders NEC</b></i>		
Periarthritis	3	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	105	0
Joint noise	1	0
Joint stiffness	2	0
Joint swelling	4	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	2	0
Myalgia	156	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	5	0
Muscle spasms	27	0
Muscle swelling	1	0
Muscle tightness	3	0
Muscle twitching	9	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	13	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Growth retardation	1	0
Mobility decreased	1	0
Muscle contracture	1	0
Musculoskeletal stiffness	28	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	43	0
Limb discomfort	25	0
Musculoskeletal chest pain	4	0
Musculoskeletal pain	2	0
Neck pain	30	0
Pain in extremity	206	0
Sacral pain	1	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	2	0
Groin pain	3	0
Neck mass	1	0
<i><b>Spondyloarthropathies</b></i>		
Arthritis reactive	3	0
<i><b>Tendon disorders</b></i>		
Trigger finger	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders cont'd		
Muscle & tissue disorders SOC TOTAL	703	0

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Skin neoplasms benign</i>		
Haemangioma of skin	1	0
Skin papilloma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Autonomic nervous system disorders</i>		
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
Dysstasia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	2	0
Lethargy	20	0
Loss of consciousness	12	0
Somnolence	8	0
Syncope	33	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	8	0
Facial paralysis	2	0
Facial spasm	1	0
<i>Headaches NEC</i>		
Cluster headache	3	0
Headache	360	0
New daily persistent headache	1	0
Sinus headache	2	0
Tension headache	10	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	4	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	8	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	47	0
Migraine with aura	3	0
Retinal migraine	1	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	2	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	1	0
<i>Neurological signs and symptoms NEC</i>		

## Case Series Drug Analysis Print

### Name: Covid-19 Moderna Vaccine Analysis Print (VAP)

Report Run Date: 22-Nov-2021

Data Lock Date: 21-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Dizziness	149	0
Dizziness postural	7	0
Head discomfort	3	0
Persistent postural-perceptual dizziness	1	0
Presyncope	5	0
Unresponsive to stimuli	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	2	0
Parosmia	1	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	6	0
Hemianaesthesia	1	0
Hyperaesthesia	6	0
Hypoaesthesia	47	0
Paraesthesia	47	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Monoparesis	4	0
Paralysis	1	0
Paresis	1	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	1	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	2	0
Febrile convulsion	1	0
Seizure	7	0
Status epilepticus	2	0
<b>Sensory abnormalities NEC</b>		
Ageusia	8	0
Allodynia	1	0
Dysgeusia	14	0
Neuralgia	5	0
Restless legs syndrome	3	0
Sensory loss	3	0
Taste disorder	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	1	0
Speech disorder	1	0
<b>Tremor (excl congenital)</b>		
Tremor	28	0
<b>Nervous system disorders SOC TOTAL</b>	<b>903</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: Covid-19 Moderna Vaccine Analysis Print (VAP)

Report Run Date: 22-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	5	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	1	0
Pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>8</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: Covid-19 Moderna Vaccine Analysis Print (VAP)

Report Run Date: 22-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<i>Product contamination and sterility issues</i>		
Product contamination physical	1	0
<b>null SOC TOTAL</b>	<b>1</b>	<b>0</b>



## Case Series Drug Analysis Print

### Name: Covid-19 Moderna Vaccine Analysis Print (VAP)

Report Run Date: 22-Nov-2021

Data Lock Date: 21-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Affect alterations NEC</i></b>		
Flat affect	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	3	0
Anxiety	17	0
Nervousness	1	0
Stress	3	0
Tension	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Social avoidant behaviour	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Mental fatigue	4	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	7	0
Disorientation	3	0
<b><i>Depressive disorders</i></b>		
Depression	4	0
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	22	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	6	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional disorder	1	0
Irritability	6	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	4	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	5	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	10	0
Feeling of despair	1	0
<b><i>Orgasmic disorders and disturbances</i></b>		
Orgasmic sensation decreased	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	4	0
Nightmare	3	0
Sleep terror	1	0
<b><i>Perception disturbances NEC</i></b>		
Derealisation	1	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	1	0
<b><i>Sexual desire disorders</i></b>		
Libido decreased	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	3	0
<b><i>Somatic symptom disorders</i></b>		
Conversion disorder	1	0
Habit cough	1	0
<b><i>Speech and language usage disturbances</i></b>		

# Case Series Drug Analysis Print

## Name: Covid-19 Moderna Vaccine Analysis Print (VAP)

Report Run Date: 22-Nov-2021

Data Lock Date: 21-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Disorganised speech	1	0
<b><i>Stereotypies and automatisms</i></b>		
Head banging	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Suicidal ideation	1	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>124</b>	<b>0</b>

# Case Series Drug Analysis Print

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Report Run Date: 22-Nov-2021

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MedDRA Version: MedDRA 24.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Bladder pain	2	0
Pollakiuria	2	0
Urinary incontinence	1	0
<i>Bladder disorders NEC</i>		
Urinary bladder haemorrhage	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	2	0
Renal pain	9	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: Covid-19 Moderna Vaccine Analysis Print (VAP)

Report Run Date: 22-Nov-2021

Data Lock Date: 21-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast pain	8	0
Breast swelling	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	1	0
Painful ejaculation	1	0
<i><b>Menopausal effects NEC</b></i>		
Premature menopause	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	42	0
Intermenstrual bleeding	18	0
Menstrual disorder	37	0
Menstruation irregular	45	0
Premenstrual dysphoric disorder	1	0
Premenstrual pain	2	0
Premenstrual syndrome	2	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	7	0
Hypomenorrhoea	10	0
Menstruation delayed	78	0
Oligomenorrhoea	3	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	72	0
Polymenorrhoea	11	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Ovulation pain	1	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Adnexa uteri pain	3	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular pain	3	0
Testicular swelling	1	0
<i><b>Uterine disorders NEC</b></i>		
Endometriosis	3	0
<i><b>Uterine tone disorders</b></i>		
Uterine spasm	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	27	0
Vulval haemorrhage	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>384</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 22-Nov-2021

Data Lock Date: 21-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	49	0
Hypopnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	3	0
Wheezing	7	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	32	0
Productive cough	3	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	3	0
Pulmonary pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	12	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	1	0
Pharyngeal swelling	4	0
<i>Pleural infections and inflammations</i>		
Pleurisy	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	3	0
<i>Respiratory signs and symptoms NEC</i>		
Respiratory symptom	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	4	0
Dysphonia	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	33	0
Paranasal sinus discomfort	2	0
Rhinorrhoea	13	0
Sinus pain	5	0
Sneezing	4	0
Throat irritation	1	0
Throat tightness	4	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>195</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 22-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	5	0
<b><i>Alopecias</i></b>		
Alopecia	2	0
<b><i>Angioedemas</i></b>		
Angioedema	5	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	12	0
Hyperhidrosis	63	0
Miliaria	7	0
Night sweats	14	0
<b><i>Bullous conditions</i></b>		
Blister	3	0
Dermatitis bullous	1	0
Erythema multiforme	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	10	0
Pain of skin	9	0
Papule	3	0
Scar pain	1	0
Sensitive skin	7	0
Skin burning sensation	3	0
Skin discolouration	2	0
Skin lesion	1	0
Skin reaction	15	0
Skin swelling	2	0
Skin warm	15	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	2	0
Dermatitis allergic	13	0
Dermatitis atopic	1	0
Dermatitis contact	1	0
Dyshidrotic eczema	2	0
Eczema	7	0
Skin irritation	4	0
<b><i>Erythemas</i></b>		
Erythema	87	0
<b><i>Exfoliative conditions</i></b>		
Exfoliative rash	1	0
Skin exfoliation	1	0
<b><i>Hyperpigmentation disorders</i></b>		
Ephelides	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	1	0
<b><i>Photosensitivity and photodermatitis conditions</i></b>		
Photosensitivity reaction	1	0
<b><i>Pilar disorders NEC</i></b>		
Piloerection	3	0
<b><i>Pruritus NEC</i></b>		
Pruritus	191	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	1	0
<b><i>Purpura and related conditions</i></b>		

## Case Series Drug Analysis Print

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Report Run Date: 22-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Purpura	1	0
<b>Rashes, eruptions and exanthems NEC</b>		
Rash	232	0
Rash erythematous	84	0
Rash macular	13	0
Rash morbilliform	1	0
Rash papular	21	0
Rash pruritic	67	0
Rash vesicular	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	2	0
Skin mass	1	0
<b>Skin dystrophies</b>		
Keloid scar	1	0
<b>Urticarias</b>		
Mechanical urticaria	1	0
Urticaria	33	0
<b>Skin disorders SOC TOTAL</b>	<b>956</b>	<b>0</b>

# Case Series Drug Analysis Print

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Report Run Date: 22-Nov-2021

Data Lock Date: 21-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menopause	1	0
<b>Social circumstances SOC TOTAL</b>	<b>1</b>	<b>0</b>



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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	1	0
<i>Immunisations</i>		
Immunisation	2	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Injection	2	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>6</b>	<b>0</b>

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Haemorrhages NEC</i>		
Haemorrhage	21	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	5	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Infarction	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	2	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	2	0
Hot flush	17	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	6	0
Poor peripheral circulation	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	4	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>66</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>6437</b>	<b>3</b>
<b>TOTAL REPORTS</b>	<b>1891</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>3</b>