

## Listing of AEFI reports received through CIR up to 11/9/2021

**Essential information about this data:**

An assessment of the safety of Comirnaty vaccine cannot be made using only the information contained in this spreadsheet. Patients are advised NOT to make any decisions about vaccination based on information contained here.

What to remember when viewing this information:

The likelihood of experiencing an adverse reaction to Comirnaty cannot be estimated from this database as the extent of under-reporting is not known.

For these reasons, it is also not possible to directly compare the risks of Comirnaty with other vaccines.

Reports (including CIR reports) are sent to the Centre for Adverse Reactions Monitoring (CARM) if the reporter suspects that Comirnaty caused an event. This does not necessarily mean that Comirnaty caused the reaction. CARM and Medsafe staff consider many factors when assessing whether a medicine has caused an adverse reaction.

The number of reports for a medicine can be influenced by how many patients are taking the medicine, media attention, the nature of the reactions, and other factors which vary over time.

The quality of the information here is limited by the quality of the original report.

The information shown here will change over time due to quality control procedures and/or receipt of further information. Reactions may also be caused by other ingredients in the medicine (excipients). The information here does not represent all the available information on the benefits and risks of Comirnaty. This information should not be used in isolation when making treatment decisions.

Any vaccination concerns should be discussed with a healthcare professional. Patients are advised not to make any vaccination decision based on the information contained here.

The reporting channel can not be used to identify how soon after the vaccine, or where the event took place.

<b>Preferred term</b>	<b># reported cases</b>
Dizziness (10013573)	3125
Nausea (10028813)	1122
Headache (10019211)	748
Syncope (10042772)	691
Hypoaesthesia (10020937)	449
Injection site pain (10022086)	404
Hypertension (10020772)	347
Chest discomfort (10008469)	315
Tachycardia (10043071)	312
Lethargy (10024264)	300
Rash (10037844)	231
Paraesthesia (10033775)	219
Anxiety (10002855)	213
Vomiting (10047700)	189
Dyspnoea (10013968)	185
Throat tightness (10043528)	184
Presyncope (10036653)	178
Pallor (10033546)	176
Depressed level of consciousness (10012373)	170
Urticaria (10046735)	164
Pruritus (10037087)	163
Feeling hot (10016334)	156

Flushing (10016825)	151
Pyrexia (10037660)	144
Hyperhidrosis (10020642)	137
Paraesthesia oral (10057372)	137
Swelling (10042674)	129
Vision blurred (10047513)	91
Palpitations (10033557)	90
Anaphylactic reaction (10002198)	88
Dysgeusia (10013911)	82
Abdominal pain (10000081)	79
Injection site swelling (10053425)	75
Hypotension (10021097)	70
Pain in extremity (10033425)	64
Injection site urticaria (10022107)	61
Tremor (10044565)	61
Seizure (10039906)	56
Malaise (10025482)	55
Wheezing (10047924)	50
Throat irritation (10043521)	48
Arthralgia (10003239)	46
Feeling of body temperature change (10061458)	46
Cough (10011224)	45
Cold sweat (10009866)	44
Bradycardia (10006093)	36
Injection site erythema (10022061)	35
Musculoskeletal pain (10028391)	32
Visual impairment (10047571)	26
Injection site pruritus (10022093)	25
Fatigue (10016256)	24
Muscle twitching (10028347)	24
Rash pruritic (10037884)	22
Lip swelling (10024570)	21
Myalgia (10028411)	21
Tinnitus (10043882)	20
Oedema peripheral (10030124)	19
Angioedema (10002424)	18
Hot flush (10060800)	18
Injection site paraesthesia (10022088)	18
Chills (10008531)	17
Face oedema (10016029)	17
Feeling cold (10016326)	17
Injection site rash (10022094)	17
Swollen tongue (10042727)	17
Rash erythematous (10037855)	16
Chest pain (10008479)	14
Injection site haemorrhage (10022067)	14
Somnolence (10041349)	14
Pain (10033371)	13
Agitation (10001497)	12
Back pain (10003988)	12

Depersonalisation/derealisation disorder (10077805)	12
Diarrhoea (10012735)	12
Dry mouth (10013781)	12
Hyperventilation (10020910)	12
Influenza like illness (10022004)	11
Injection site warmth (10022112)	11
Musculoskeletal stiffness (10052904)	11
Dysphagia (10013950)	10
Oropharyngeal pain (10068319)	10
Oxygen saturation decreased (10033318)	10
Asthma (10003553)	9
Feeling abnormal (10016322)	9
Abdominal discomfort (10000059)	8
Asthenia (10003549)	8
Bronchospasm (10006482)	8
Dysphonia (10013952)	8
Eructation (10015137)	8
Hypoacusis (10048865)	8
Lymphadenopathy (10025197)	8
Periorbital oedema (10034545)	8
Pharyngeal swelling (10082270)	8
Tongue disorder (10043951)	8
Vertigo (10047340)	8
Burning sensation (10006784)	7
Injection site inflammation (10022078)	7
Muscular weakness (10028372)	7
Neuralgia (10029223)	7
Tachypnoea (10043089)	7
Blood pressure fluctuation (10005746)	6
Disorientation (10013395)	6
Dysarthria (10013887)	6
Erythema (10015150)	6
Hypoaesthesia oral (10057371)	6
Limb discomfort (10061224)	6
Muscle tightness (10049816)	6
Rhinitis (10039083)	6
Thirst (10043458)	6
Anaphylactoid reaction (10002216)	5
Dry throat (10013789)	5
Epistaxis (10015090)	5
Eye pain (10015958)	5
Facial paralysis (10016062)	5
Gait disturbance (10017577)	5
Head injury (10019196)	5
Ocular hyperaemia (10030041)	5
Panic reaction (10033670)	5
Angina pectoris (10002383)	4
Confusional state (10010305)	4
Cyanosis (10011703)	4
Decreased appetite (10061428)	4

Dehydration (10012174)	4
Eye pruritus (10052140)	4
Hypoglycaemia (10020993)	4
Hypokinesia (10021021)	4
Injection site bruising (10022052)	4
Migraine (10027599)	4
Muscle spasms (10028334)	4
Nasal congestion (10028735)	4
Rash maculo-papular (10037868)	4
Rhinorrhoea (10039101)	4
Aphasia (10002948)	3
Arrhythmia (10003119)	3
Arthropod sting (10003402)	3
Atrial fibrillation (10003658)	3
Generalised tonic-clonic seizure (10018100)	3
Herpes zoster (10019974)	3
Hypoxia (10021143)	3
Injection site hypoaesthesia (10074586)	3
Lip disorder (10048470)	3
Loss of consciousness (10024855)	3
Nervousness (10029216)	3
Pain in jaw (10033433)	3
Product administration error (10081576)	3
Respiratory disorder (10038683)	3
Retching (10038776)	3
Salivary hypersecretion (10039424)	3
Speech disorder (10041466)	3
Stridor (10042241)	3
Tearfulness (10043169)	3
Ataxia (10003591)	2
Bronchitis (10006451)	2
Diplopia (10013036)	2
Eye discharge (10015915)	2
Eye irritation (10015946)	2
Facial pain (10016059)	2
Fall (10016173)	2
Feeling drunk (10016330)	2
Feeling jittery (10016338)	2
Hemiplegia (10019468)	2
Hypersensitivity (10020751)	2
Injection site haematoma (10022066)	2
Injection site mass (10022081)	2
Injury associated with device (10069803)	2
Localised oedema (10048961)	2
Lymphadenitis (10025188)	2
Mouth ulceration (10028034)	2
Nasal discomfort (10052437)	2
Oedema mouth (10030110)	2
Pericarditis (10034484)	2
Photophobia (10034960)	2

Pulse abnormal (10037466)	2
Urinary incontinence (10046543)	2
Alopecia (10001760)	1
Amnesia (10001949)	1
Apnoea (10002974)	1
Arrhythmia supraventricular (10003130)	1
Arterial thrombosis (10003178)	1
Breath holding (10006322)	1
Deep vein thrombosis (10051055)	1
Defaecation urgency (10012110)	1
Depression (10012378)	1
Dyspepsia (10013946)	1
Ear disorder (10014004)	1
Ear pain (10014020)	1
Ecchymosis (10014080)	1
Electric shock sensation (10014358)	1
Electrocardiogram abnormal (10014363)	1
Eyelid oedema (10015993)	1
Fibromyalgia (10048439)	1
Frequent bowel movements (10017367)	1
Gastritis (10017853)	1
Gastrooesophageal reflux disease (10017885)	1
Guillain-Barre syndrome (10018767)	1
Haematuria (10018867)	1
Hallucination, visual (10019075)	1
Hepatic enzyme increased (10060795)	1
Hyperaesthesia (10020568)	1
Hypopnoea (10021079)	1
Hypotonic-hyporesponsive episode (10021121)	1
Injection site cellulitis (10050057)	1
Injection site coldness (10050082)	1
Injection site discomfort (10054266)	1
Injection site hyperaesthesia (10073418)	1
Injection site irritation (10022079)	1
Injection site reaction (10022095)	1
Insomnia (10022437)	1
Intermenstrual bleeding (10022559)	1
Lip dry (10024552)	1
Lip ulceration (10024572)	1
Meningitis (10027199)	1
Menstrual disorder (10027327)	1
Miliaria (10027627)	1
Muscle contractions involuntary (10028293)	1
Mydriasis (10028521)	1
Myocardial infarction (10028596)	1
Myoclonus (10028622)	1
Orthostatic hypotension (10031127)	1
Paraesthesia mucosal (10033780)	1
Peripheral coldness (10034568)	1
Petechiae (10034754)	1

Photopsia (10034962)	1
Photosensitivity reaction (10034972)	1
Pulmonary embolism (10037377)	1
Rash macular (10037867)	1
Rosacea (10039218)	1
Scleritis (10039705)	1
Sinusitis (10040753)	1
Skin irritation (10040880)	1
Sleep disorder (10040984)	1
Synovitis (10042868)	1
Thrombosis (10043607)	1
Transient ischaemic attack (10044390)	1
Vasculitis (10047115)	1

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