

## COVID-19 Vaccine Novavax Vaccine Analysis Print

Report Run Date: 30-Nov-2022  
Data Lock Date: 23-Nov-2022 18:30:06

All UK spontaneous reports received up to and including 23/11/22 for COVID-19 Vaccine Novavax. 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.

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Earliest Reaction Date: 20-Dec-2020

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	3	0
Vomiting	1	0
<i>Tooth missing</i>		
Tooth loss	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	1	0
Fatigue	4	0
Malaise	2	0
<i><b>Febrile disorders</b></i>		
Pyrexia	1	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	2	0
Feeling abnormal	1	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	1	0
<i><b>General signs and symptoms NEC</b></i>		
Influenza like illness	1	0
Unevaluable event	1	0
<i><b>Pain and discomfort NEC</b></i>		
Chest pain	1	0
Pain	1	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Adverse drug reaction	3	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site movement impairment	1	0
Vaccination site pain	2	0
<b>General disorders SOC TOTAL</b>	<b>22</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Coronavirus infections</i>		
Breakthrough COVID-19	1	0
COVID-19	2	0
<i>Herpes viral infections</i>		
Herpes virus infection	1	0
Herpes zoster	1	0
<b>Infections SOC TOTAL</b>	<b>5</b>	<b>0</b>

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<b>Injuries</b>		
<i>Non-site specific injuries NEC</i>		
Injury	1	0
<i>Off label uses</i>		
Off label use	15	0
<i>Product administration errors and issues</i>		
Product administered at inappropriate site	1	0
<b>Injuries SOC TOTAL</b>	<b>17</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Investigations</b>		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
<b>Investigations SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Muscle &amp; tissue disorders</b>		
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Neck pain	1	0
Pain in extremity	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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<b>Nervous system disorders</b>		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Coordination and balance disturbances</i>		
Dysstasia	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Headaches NEC</i>		
Headache	2	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	3	0
Dizziness postural	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	1	0
Paraesthesia	2	0
<b>Nervous system disorders SOC TOTAL</b>	<b>16</b>	<b>0</b>

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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>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Reproductive &amp; breast disorders</b>		
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Throat irritation	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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<b>Skin disorders</b>		
<i><b>Alopecias</b></i>		
Alopecia	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Acute febrile neutrophilic dermatosis	1	0
<i><b>Dermatitis and eczema</b></i>		
Eczema	1	0
<i><b>Purpura and related conditions</b></i>		
Purpura	1	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	1	0
Rash macular	1	0
Rash pruritic	1	0
<b>Skin disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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<b>Surgical &amp; medical procedures</b>		
<i>Immunisations</i>		
COVID-19 immunisation	9	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>9</b>	<b>0</b>

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<b>Vascular disorders</b>		
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	2	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>106</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>52</b>	