

Reported suspected adverse reactions to COVID-19 vaccines as of 01.03.2022

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About the report

- Since January 2021, the Norwegian Medicines Agency has published a weekly report presenting information on suspected adverse reactions to COVID-19 vaccines which have been assessed. From November 2021, these reports have been published less frequently. From January 2022, the report will be published every two weeks.
- The adverse reaction reports in the report are submitted by patients, health professionals and producers.
- Symptoms or illnesses that occur after vaccination are reported if there is any *suspicion* of a possible link. As a result, it cannot be assumed that there is a causal relationship between the suspected adverse reaction and the vaccine.
- The report summarises all reports of suspected adverse reactions that have been treated. As a result, there is a difference between the number of reports which have been received and those which have been assessed, because reports are continually being assessed.
- All reports are counted, regardless of whether or not the event being reported is believed to be linked to vaccination.
- The fact that a report has been assessed means that the severity of the incident has been determined, and the symptoms have been translated into international terminology and categorised (see Appendix 1).
- We prioritise and assess serious reports of suspected adverse reactions first. The reports therefore does not give a true picture of the distribution between serious and non-serious events.
- The reports provide a snapshot of the adverse reactions at the time of reporting and rarely contain complete information about the event. The interpretation and assessment of causality are based on the information that is available at the time of reporting.
- The reporting scheme is a vital tool in the monitoring of vaccines. The reports submitted by health professionals and members of the public give us signals as to whether there are any events that we should investigate further. It is not known with any certainty what proportion of these events are being reported, while a report does not necessarily indicate a causal relationship. As a result, the number of reports submitted to the Norwegian Medicines Agency cannot normally be used to determine how often or how many adverse reactions a vaccine could give rise to, or to compare the safety profiles of different vaccines.
- The term “temporal link” between vaccination and an adverse reaction is used in the report. “Temporal link” is not a precisely defined time period, but six weeks is often used as a guide for health professionals when they are assessing whether adverse reactions have occurred with a temporal link to vaccination. Some adverse reactions can occur after more than six weeks have elapsed and may still be suspected as being linked to vaccination. As long as the person submitting the report suspects there may be a link between vaccination and the adverse reaction, the report will be counted, regardless of how long has passed since vaccination.

Summary

This report is based on reports that are assessed until 01 March 2022. The assessed adverse reaction reports do not provide a basis for revising the current overall recommendations regarding the use of the vaccines.

More reports than expected indicate a good reporting culture

The Norwegian Medicines Agency receives many reports and has found that both health professionals and the general population have a low threshold for reporting suspected adverse reactions following vaccination against COVID-19. There may be a number of reasons why we are receiving large numbers of reports:

- A high proportion of the population has been or will be vaccinated over a short period of time.
- The COVID-19 vaccines tend to cause strong reactions in more people than we are accustomed to with other vaccines. More people are therefore experiencing common adverse reactions.
- It has become much easier to report suspected adverse reactions online. Health professionals previously had to fill in a paper form.
- The provision of clear information about adverse reactions means that health professionals and the population are more aware and tend to report reactions more readily.
- Health professionals are obliged to report suspected adverse reactions following vaccination.

Common and known adverse reactions

Most reports of adverse reactions following COVID-19 vaccination, regardless of the type of vaccine used, concern common and transient adverse reactions such as headache, fatigue, malaise, fever, nausea and pain in the body. These usually appear on the first or second day after vaccination and last around two to three days. These are known adverse reactions which are described in the product information for the vaccines.

Serious adverse reactions

Most of the serious suspected adverse reactions which have been reported concern medical conditions or symptoms which are relatively common in the population. The timing of the events soon after vaccination may therefore be coincidental. Reports of serious events are given priority and assessed before non-serious reports. Serious reports are discussed in a separate section on [page 5](#).

Adverse reaction news:

Together with this report, we publish a news article discussing topical issues.

[Click here to read news article](#)

Vaccines in the COVID-19 vaccination programme

- Comirnaty (BioNTech/Pfizer), mRNA vaccine
- Spikevax (Moderna), mRNA vaccine
- Nuvaxovid (Novavax), protein-based vaccine

Vaccines withdrawn from or offered outside the COVID-19 vaccination programme:

- The Janssen COVID-19 vaccine is offered, but not as part of the vaccination programme.
- Vaxzevria (AstraZeneca): In May 2021, the government decided to withdraw this vaccine from the Norwegian vaccination programme.

Key figures as of 01.03.2022

From the start of the vaccination programme in Norway on 27 December 2020 through to 01 March 2022, **57,858** reports of suspected adverse reactions have been received following COVID-19 vaccination; **29,465 (51 %)** of these have been assessed. The fact that the reports have been assessed means that they have been classified and sorted, but not necessarily that a final assessment of causality has been made in all cases.

The number of reports must be interpreted in light of the number of people who have been vaccinated. As of 01 March 2022, a total of **11,224,000** doses of COVID-19 vaccines have been administered in Norway. Over **4,321,000** people have received their first dose of vaccine, over **4,020,000** have received their second dose and over **2,882,000** received their third dose (Source: SYSVAK, <https://statistikk.fhi.no/sysvak>).

Table 1: Distribution of reports by gender

Gender	Female	Male	Unknown gender
Total number of reports	23 650	5 797	24
Number of serious reports	3 809	1 769	11

** The table shows number of reports that have been assessed.*

Comment on Table 1:

Numerous studies have indicated that women are more likely than men to contact the health service and report adverse reactions.

Table 2: Distribution of reports by age

	Age group											Total
	5-11	12-17	18-29	30-39	40-49	50-59	60-69	70-79	80-89	90+	Unknown age	
Serious reports	<5	71	797	910	1034	1 071	672	465	289	127	153	5 589
Non serious reports	5	427	5 221	5 804	5 096	3 645	1 552	627	322	129	1 048	23 876
Total	<10	498	6 018	6 714	6 130	4 716	2 224	1092	611	256	1 201	29 465

*The table shows number of reports that have been assessed.
Excluding reports concerning the under 5 age group. See the separate section in the remarks below.*

Comment on Table 2:

A total of 20 reports have been received and assessed regarding children under the age of 5 who are being breastfed. The children have not been vaccinated themselves, but the mother had been vaccinated. Various symptoms have been reported in the children, including fever, abdominal pain, nausea, anxiety, rash or cold. In most of the children, the symptoms appeared 0-3 days after the mother had been vaccinated. Such symptoms are very common in infants and toddlers and are probably not due to the mother receiving the mRNA vaccine. The mRNA from the vaccines is not passed in breast milk.

Events following vaccination are reported on the basis of suspicions and there is not necessarily any causal relationship. All reports are included in the report, regardless of whether or not an event is believed to be linked to vaccination.

Reports concerning pregnant women are monitored particularly closely

In Norway, the vaccination rate amongst pregnant women has risen over the past six months. Of all the women who gave birth in January 2022, 70% had been vaccinated against COVID-19. We have received and assessed 118 reports concerning events linked to pregnancy, childbirth and newborn babies where the mother had been vaccinated. Reports concerning pregnant women are often automatically classified as serious. The vast majority of reports concern complications which are common during pregnancy, such as miscarriage and bleeding. If these complications arise shortly after vaccination, we would expect to receive such reports. Studies show that there is no increase in the risk of miscarriage following vaccination.

Health professionals have a low threshold for reporting and informing us about events following vaccination so that we can follow the cases up. We pay particular attention to reports concerning pregnant women. Together with the National Institute of Public Health, we are conducting ongoing studies in order to check whether there is an increased incidence of pregnancy complications or illness in the mother and child where the mother has been vaccinated.

We are working closely with clinical experts both in Norway and internationally to acquire information from birth registries and other sources. No increase in the incidence of complications in pregnancy or disease amongst newborn babies following vaccination of the mother has so far been observed.

Pregnant women are at greater risk of severe COVID-19 disease, which can have serious consequences for both mother and child. Serious cases of disease have also been reported in pregnant women after infection with omicron. The Norwegian Institute of Public Health therefore recommends that pregnant women be vaccinated.

Reports classified as serious

So far, 5,589 reports of events which are classified as serious have been assessed. This accounts for 19 % of all reports which have been assessed. We prioritise the assessment of serious reports first, so that reports that have not been assessed are virtually all non-serious reports.

What types of events are classified as serious

Reports of adverse reactions are generally classified as serious when the event:

- results in or extended a stay in hospital

- results in a prolonged reduction in function level
- results in life-threatening illness or death
- results in birth defects/congenital malformations
- is on the EMA's list of important medical events (Important medical event (IME) list)

Hospital admission is the most common reason why an event is classified as serious, and this applies to 49 %* of serious reports. In these cases, the descriptions provided by the person submitting the report cover everything from patients who are only kept under observation for a short period of time and go on to recover quickly, to patients with a life-threatening symptoms and illness which results in permanent injury.

* The Norwegian Medicines Agency previously made an error when it calculated the proportion of adverse reactions that resulted in hospital admission. We calculated the proportion relative to the number of severity criteria specified in the reports. This is incorrect, as an adverse reaction report can fulfil several severity criteria.

The aim has always been to calculate the proportion of reports that have resulted in hospital admission relative to the total number of serious reports. The percentage share was corrected from the report on adverse reactions as of 4 January 2022 onwards.

IME-list

The EMA has compiled a list of important medical events which are always to be classified as serious (the IME list). The summary below lists the conditions on the IME list which are most frequently reported following COVID-19 vaccination (in descending order).

- vaginal bleeding after menopause
- fainting (syncope)
- pericarditis
- blood clot in the lungs
- myocarditis
- deep vein thrombosis
- anaphylactic reaction
- blood clots (thrombosis)
- abnormal heart rhythms (arrhythmia)
- blood clots or bleeding in the brain

Most of the serious suspected adverse reactions which have been reported concern medical conditions which are relatively common in the population. The timing of the events may therefore be coincidental.

Reactions which health professionals should be aware of

Other serious events have also been observed following vaccination where no causal relationship has been established. The Norwegian Medicines Agency wishes healthcare professionals to be aware of the following conditions in persons who are vaccinated:

- chest pain and breathing difficulties
- numbness
- reduced sensation and paralysis
- lasting symptoms, such as long-lasting headache or vaginal bleeding

Table 3: Distribution of reports of suspected adverse reactions according to severity.

Vaccine	Comirnaty (BioNTech/Pfizer)			Spikevax (Moderna)			Vaxzevria (AstraZeneca)	COVID-19 Vaccine Janssen
	1.dose	2. dose	3. dose	1.dose	2. dose	3. dose	1.dose	1.dose
Number of doses administered	3 618 702	2 973 400	2 218 990	552 187	1 041 951	663 454	142 926 ***	6 842
Total number of reports	15 442*			5 240*			8 949*	31*
Number of reports involving death	231**			18**			6**	0**
Serious reports other than death	3 574			1 145			690	4
Non-serious reports	11 637			4 077			8 253	27
	<p><i>*The table shows number of reports that have been assessed</i></p> <p><i>**The fact that a person dies soon after being vaccinated does not necessarily mean that there is a causal relationship.</i></p> <p><i>***Vaxzevria has not been administered in Norway since 11 March, but number of doses administered may continue to increase as it reflects post-registration of doses administered abroad. Post-registration of vaccines administered abroad may effect the number of doses administered for all the coronavirus vaccines.</i></p>							

Comment on Table 3:

The data concerning the various coronavirus vaccines are not directly comparable. The vaccines have been administered to a different number of people with different disease profile and ages.

Reports on deaths

So far, 255 reports of deaths have been assessed. There is a temporal link between some of the deaths and vaccination, while other deaths are due to Covid-19 in fully vaccinated people several months after the last dose. Most deaths have occurred amongst elderly persons receiving nursing care and residents of nursing homes.

Amongst the 255 deaths, 16 reports relate to deaths in fully vaccinated people who have been diagnosed with COVID-19. The patients who died was diagnosed with COVID-19 from 2 to 10 months after vaccination, and the events are reported due to suspected vaccination failure. [Breakthrough infection was discussed in the report from 28. September 2021.](#)

Persons over the age of 60

Every week, more than 300 residents die in Norwegian nursing homes and other similar institutions. Many of the elderly nursing home residents who have been vaccinated are very frail or terminally ill patients. It is therefore to be expected that deaths will occur with a temporal link to vaccination, without there necessarily being any causal link to the vaccine. The reports on many of these deaths in the elderly state that no link with vaccination is suspected, and that the death is being reported for the sake of completeness.

[An expert group of geriatric specialists have looked into the first 100 deaths that were reported after Comirnaty.](#) There is some uncertainty regarding the assessments, but in 10 cases a causal relationship between vaccination and death was considered to be "probable". In these cases, it was apparent that common vaccine adverse reactions may have contributed to more serious illness.

Persons under the age of 60

We have assessed 20 reports of deaths following vaccination in people under the age of 60. Four of these cases concern deaths resulting from the very rare, but serious adverse reaction known as thrombosis with thrombocytopenia syndrome (TTS) following vaccination with Vaxzevria. For the remaining deaths, the causal relationship with vaccination is uncertain.

Reports on pericarditis and myocarditis after vaccination with mRNA-vaccine

A number of cases of pericarditis (inflammation of the lining around the heart) and myocarditis (inflammation of the heart muscle) have been observed in persons who have been vaccinated with Comirnaty or Spikevax. As of 01 March 2022, 282 cases of pericarditis and 145 cases of myocarditis have been reported in Norway after vaccination with mRNA-vaccine.

In addition there are 5 reports on pericarditis after vaccination with Vaxzevria.

It is not yet known whether those who have developed pericarditis or myocarditis after covid vaccination are at risk of recurrence after their next dose and, as a precaution, the Norwegian Institute of Public Health therefore recommends that persons who have developed these inflammatory conditions should refrain from further covid vaccination.

Table 4: Age distribution of reports on pericarditis and myocarditis after mRNA-vaccine

	Age group							
	12-29	30-39	40-49	50-59	60-69	70-89	Unknown age	Total
Pericarditis	65	54	49	46	38	27	3	282
Myocarditis	63	14	23	16	15	11	3	145

Table 5: Gender distribution of reports on pericarditis and myocarditis after mRNA-vaccine

	Female	Male
Pericarditis	113	169
Myocarditis	41	104

Reports of suspected adverse reactions in children and adolescents 5 -17 years.

On 14 January 2022, the vaccination programme was expanded to include children between the age of 5 and 11. At the same time, the programme was opened up to enable 12-15 year olds to receive two doses. We highly prioritise the assessment of reports concerning children and adolescents. We are closely monitoring the situation and are particularly alert to reports of serious events in this age group.

Adolescents normally experience the same common and transient adverse reactions as adults following vaccination.

As of 01 March 2022, over 464,000 doses have been administered to children and adolescents aged 12 to 17. During the period December 2020 to 01 March 2022, we have received and assessed 498 adverse reaction reports concerning this age group. 71 of these are classified as serious. This includes six reports of heart inflammation, pericarditis and myocarditis.

79 % of the adverse reaction reports in this age group are from girls. Many reports concern menstrual disorders. Most of these are classified as non-serious.

A total of 5,230 children aged 5 to 11 years have so far been vaccinated. We have received and assessed fewer than ten reports of suspected adverse reactions in this age group.

Menstrual cycle and uterine bleeding disorders

We have so far assessed 3,920 reports of menstrual disorders. Most of these reports concern women between the ages of 20 and 49. 429 of these reports are classified as serious.

In many of these cases, it is not the menstrual disorder, but other ailments that have been reported at the same time, which means that the report is classified as serious overall. If menstrual disorders are prolonged and affect the person's ability to work and carry out other daily chores, the report will also often be classified as serious.

We have assessed 309 reports concerning women who have suffered unexpected vaginal bleeding after menopausal age. 303 of these are classified as serious. Unexpected vaginal bleeding after menopausal age is always classified as serious if it occurs more than one year after the last menstruation.

The Norwegian Institute of Public Health (NIPH) is conducting a major study in an attempt to determine whether or not there is a link between COVID-19 vaccines and bleeding disorders. Preliminary results from NIPH's population survey show that there is an increased incidence of menstrual disorders following COVID-19 vaccination in young women aged between 18 and 30.

How can we detect new adverse reactions?

We work systematically to analyse the reports so that we can respond quickly if new combinations of symptoms arise, or if common medical conditions occur more frequently following vaccination than we would expect. We work in three different ways:

- 1. Health professionals assess individual cases of medical conditions and report when they suspect adverse reactions. The government authorities assess the reports in order to look for unknown combinations of symptoms or to determine whether there are any factors associated with the progression of the conditions which would indicate a link with vaccination.**

E.g.: It was a combination of observant doctors at Oslo University Hospital, a robust and fast electronic monitoring system and analyses by the University Hospital of Northern Norway and the Preparedness Register which enabled Norway to help reveal that, in rare cases, Vaxzevria can give rise to a serious combination of symptoms involving blood clotting and low blood platelet counts.

- 2. We carry out statistical analyses where we investigate whether the number of reports of a combination of symptoms is higher than expected.**

E.g.: Such statistical analyses of reported adverse reactions have shown that serious allergic reactions occur more frequently following COVID-19 vaccination than with vaccination with influenza vaccines. It is also such analyses that have led to myocarditis and pericarditis being included as rare adverse reactions in the product information for Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna).

- 3. Health registers and population-based cohorts are used to assess and investigate further, and to confirm or disprove possible links between vaccination and reported symptoms or diagnoses. This is done in partnership with the Norwegian Institute of Public Health.**

E.g.: Further investigation of possible links concerning symptoms reported via the spontaneous reporting system can be carried out by linking the Norwegian Immunisation Register (SYSVAK) to other health registers, to see whether any diagnoses occur more frequently following vaccination than is otherwise the case.

The Norwegian Institute of Public Health and research institutions in many countries are also conducting registry studies to see whether there is any increase in the prevalence of diseases amongst vaccinated people that are not necessarily identified through the adverse reaction reports.

Appendix 1:

Number of suspected adverse reactions according to category

A single adverse reaction report can include a number of suspected adverse reactions or symptoms. Suspected adverse reactions are presented below, grouped according to the category to which they belong for each vaccine type and the types of suspected adverse reactions which have been reported most frequently. The categories are the highest level in a hierarchical, standardised medical terminology which is used internationally (MedDRA). Using this terminology makes it possible to compare reports internationally.

Suspected adverse reactions to mRNA vaccines Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna)

The most frequently reported symptoms following vaccination with the mRNA vaccines primarily consist of known adverse reactions within the general symptoms category, and include reactions at the vaccine injection site, decreased general condition, fever and general malaise. Headache, dizziness and drowsiness after vaccination are also frequently

Figure 1: Reported suspected adverse reactions by category for mRNA vaccines Comirnaty and Spikevax

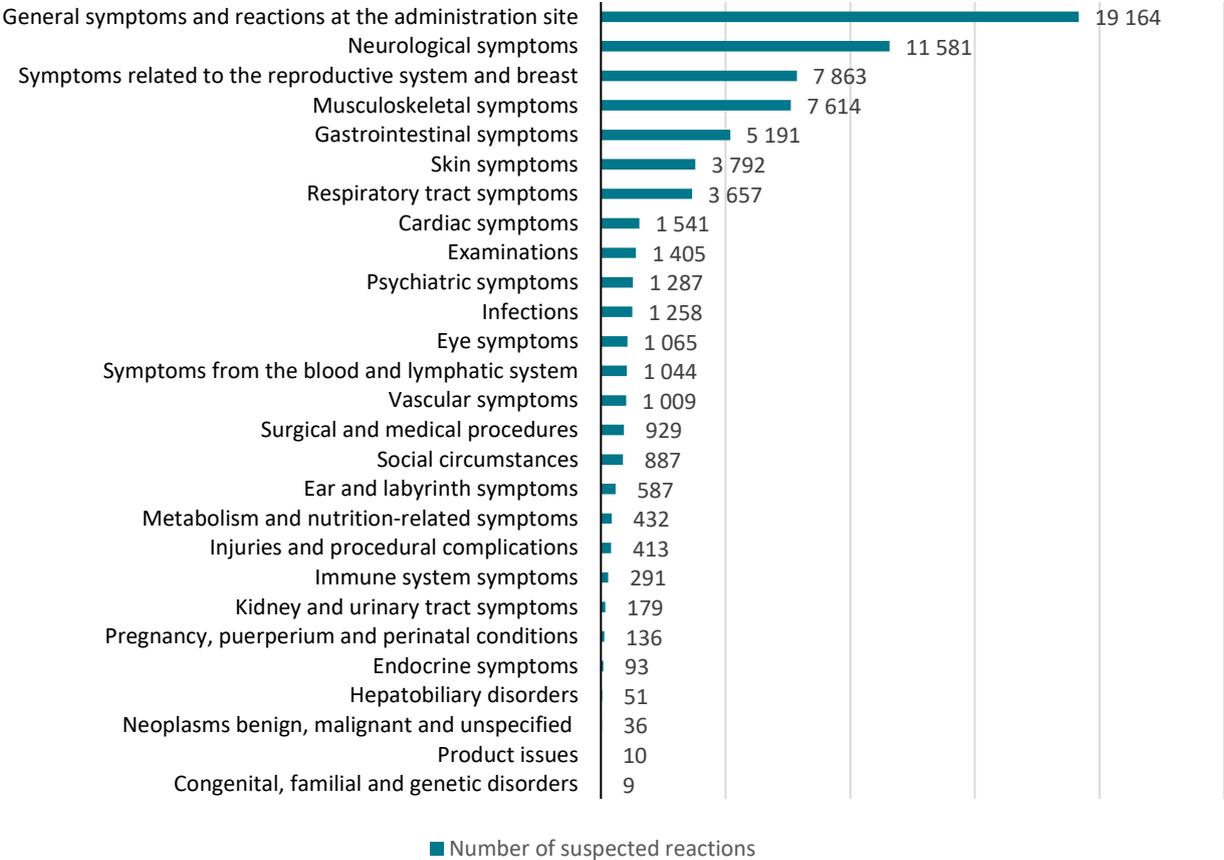


Table 6: Reported suspected adverse reactions by category for Comirnaty and Spikevax

A report can cover several adverse reactions and there will therefore be many more adverse reactions than reports.

Category	Number of suspected adverse reactions
General symptoms and reactions at the vaccine administration site E.g.: Pain and reactions at the injection site, discomfort, fever, fatigue, decreased general condition	19 164
Neurological symptoms E.g.: Headache, dizziness, drowsiness, syncope, loss of smell and taste	11 581
Symptoms relating to the reproductive organs and breast E.g.: Breast pain and menstrual disorder	7 863
Musculoskeletal symptoms E.g.: Muscle pain, joint pain, muscle stiffness, pain in the extremities	7 614
Gastrointestinal symptoms E.g.: Stomach pain, nausea, vomiting, diarrhoea	5 191
Skin symptoms E.g.: Rash, itching, redness, cold sweats, acne, night sweat	3 792
Respiratory tract symptoms E.g.: Difficulty breathing, shortness of breath, cough, irritation of the respiratory	3 657
Cardiac symptoms E.g.: Bradycardia, tachycardia, pericarditis, atrial fibrillation, extrasystoles	1 541
Examinations E.g.: Abnormal and raised heart rate, decreased blood pressure, decrease in oxygen saturation	1 405
Psychiatric symptoms E.g.: Sleep abnormalities, restlessness, lethargy, hallucination	1 287
Infections E.g.: Pneumonia, cold symptoms, shingles	1 258
Eye symptoms E.g.: Blurred vision, twitch, itchy eyes, photophobia, double vision, eye pain	1 065
Symptoms from the blood and lymphatic system E.g.: Swollen lymph nodes	1 044
Vascular symptoms E.g.: Flushes, pallor, low blood pressure, haemorrhage, deep vein thrombosis	1 009
Surgical and medical procedures E.g.: Hospitalisation, oxygen therapy, revaccination with other Covid-19 vaccine	929
Social circumstances E.g.: Bedridden, impaired work ability	887
Ear and labyrinth symptoms E.g.: Discomfort in the ear, tinnitus	587
Metabolic and nutrition-related symptoms E.g.: Reduced appetite, dehydration, high blood sugar	432
Injuries and procedural complications E.g.: Fall, bruise, wound	413
Immune system symptoms E.g.: Allergic reaction	291

Kidney and urinary tract symptoms E.g.: Urine retention, frequent urination, acute kidney injury	179
Pregnancy, puerperium and perinatal conditions E.g.: Spontaneous abortion, bleeding during pregnancy	136
Endocrine symptoms E.g.: Hypothyroidism, hyperthyroidism, thyroiditis	93
Hepatobiliary disorders E.g.: Portal vein thrombosis, hepatitis, gallstone	51
Neoplasms benign, malignant and unspecified	36
Product issues	10
Congenital, familial and genetic disorders	9

Suspected adverse reactions to viral vector vaccines Vaxzevria (AstraZeneca) and COVID-19 Vaccine Janssen (Janssen Cilag International NV)

These vaccines are not part of the Norwegian vaccination programme. Vaxzevria has not been administered in Norway since 11 March 2021. The Janssen COVID-19 vaccine is offered, but not as part of the vaccination programme. The number of suspected adverse reactions will increase if new reports are assessed. The number of suspected adverse reactions may also decrease if there are multiple reports of the same adverse reaction for the same patient (duplicates). The reports will then be merged and one of them deleted.

The most frequently reported symptoms following vaccination with the viral vector vaccines primarily consist of known adverse reactions within the general symptoms category, and include reactions at the vaccine injection site, decreased general condition, fever and general malaise. Headache, dizziness and drowsiness after vaccination are also frequently

Figure 2: Number of reported suspected adverse reactions by category for viral vector vaccines Vaxzevria and COVID -19 Vaccine Janssen

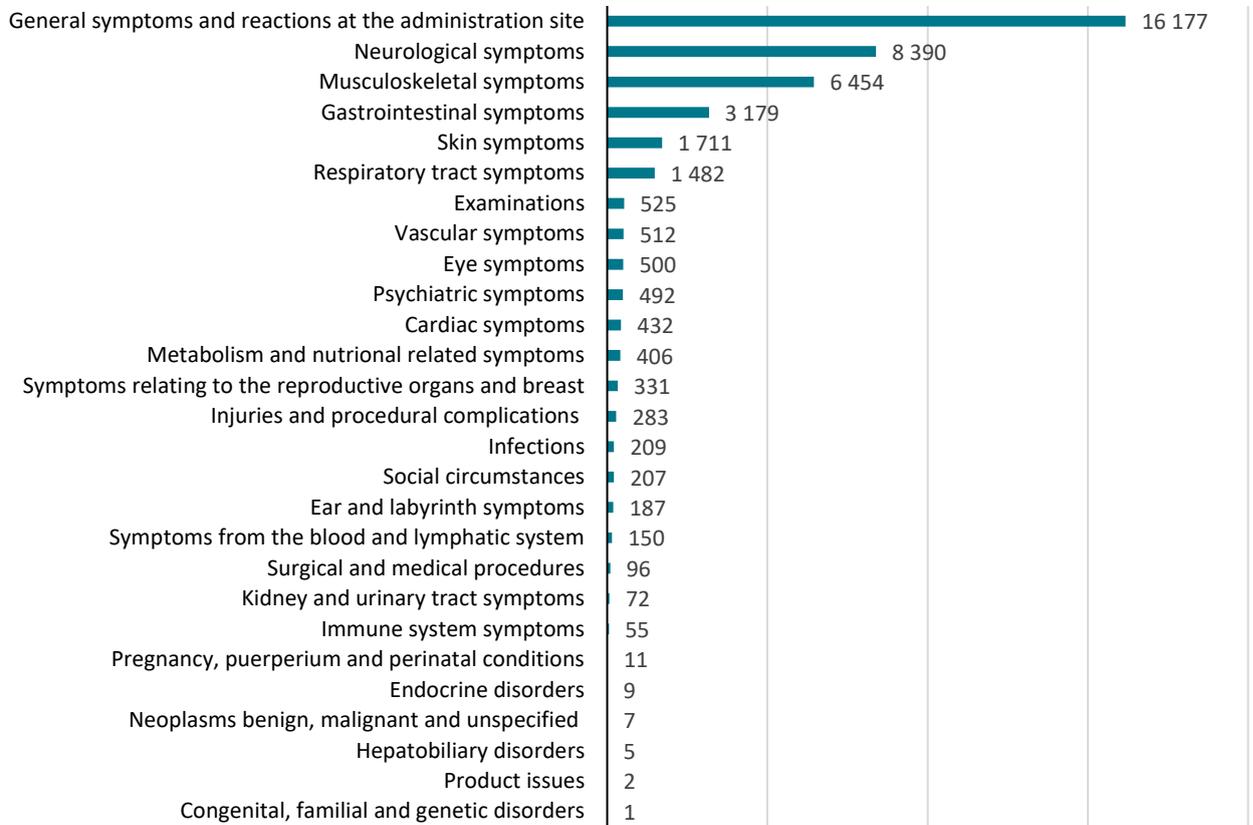


Table 7: Reported suspected adverse reactions by category for Vaxzevria and COVID-19 Vaccine Janssen

A report can cover several adverse reactions and there will therefore be many more adverse reactions than reports.

Category	Number of reported adverse reactions*
General symptoms and reactions at the vaccine administration site E.g.: Pain and reactions at the injection site, discomfort, fever, fatigue, decreased general condition	16 177
Neurological symptoms E.g.: Headache, dizziness, drowsiness, numbness	8 390
Musculoskeletal symptoms E.g.: Muscle pain, joint pain, back pain	6 454
Gastrointestinal symptoms E.g.: Stomach pain, nausea, vomiting, diarrhoea	3 179

Skin symptoms E.g.: Rash, skin pain, cold sweats	1 711
Respiratory tract symptoms E.g.: Difficulty breathing, hyperventilation, nasal congestion, pain and swelling of pharynx	1 482
Examinations E.g.: Abnormal and raised heart rate	522
Vascular symptoms E.g. Flushing	512
Eye symptoms E.g.: Blurred vision, twitch, eye pain	500
Psychiatric symptoms E.g.: Sleep abnormalities, insomnia	492
Cardiac symptoms E.g.: Palpitations	432
Symptoms relating to the reproductive organs and breast E.g. Pain in reproductive organs and nipples	406
Metabolic and nutrition-related symptoms E.g.: Reduced appetite	331
Injuries and procedural complications E.g. Contusion	283
Infections E.g. Sinus infection, cold symptoms	209
Social circumstances E.g.: Bedridden	207
Ear and labyrinth symptoms E.g.: Discomfort in the ear, sound sensitivity	187
Symptoms from the blood and lymphatic system E.g.: Swollen lymph nodes	150
Surgical and medical procedures E.g.: revaccination with different COVID-19 vaccine	96
Kidney and urinary tract symptoms E.g.: Frequent urination	72
Immune system symptoms E.g.: anaphylactic reaction, allergic reaction	55
Pregnancy, puerperium and perinatal conditions E.g.: spontaneous abortion	11
Endocrine symptoms E.g.: hyperthyroidism	9
Neoplasms, benign, malignant and unspecified	7
Hepatobiliary disorders	5
Product issues	2
Congenital, familial and genetic disorders	1

* The number of reported adverse reactions may also decrease if there are multiple reports of the same adverse reaction for the same patient (duplicates). The reports will then be merged and one of them deleted