

Reported suspected adverse reactions to COVID-19 vaccines as of 28.09.2021

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About the report

- The Norwegian Medicines Agency publishes weekly reports on treated suspected adverse reactions to COVID-19 vaccines. The adverse reaction reports 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 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.

Summary

This report is based on reports that are assessed until 28 September 2021. The assessed adverse reaction reports for this week 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.

This week's adverse reaction news:

Every week, we publish a news article discussing topical issues. Topics covered in this week's adverse reaction news:

[Click here to read this week's news](#)

Vaccines in the COVID-19 vaccination programme

Comirnaty (BioNTech/Pfizer), mRNA vaccine (given as two doses)

- Spikevax (Moderna), mRNA vaccine (given as two doses)

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 28.09.2021

From the start of the vaccination programme in Norway on 27 December 2020 through to 28 September 2021, **34,793** reports of suspected adverse reactions have been received following COVID-19 vaccination; **18,739 (54 %)** 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 28 September 2021, a total of **7,768,000** doses of COVID-19 vaccines have been administered in Norway. Over **4,142,000** people have received their first dose of vaccine, while over **3,626,000** have received their second dose (Source: SYSVAK, <https://statistikk.fhi.no/sysvak>).

Table 1: Distribution of reports by gender

Gender	Female	Male	Unknown gender
Total number of reports	15 180	3 545	14
Number of serious reports	1 988	1 031	4

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
	12-17	18-29	30-39	40-49	50-59	60-69	70-79	80-89	90+	Unknown age	
Serious reports	13	402	444	517	511	402	328	216	114	75	3 023
Non serious reports	63	3 413	3 874	3 377	2 543	1 076	469	291	124	474	15 716
Total	76	3 815	4 318	3 894	3 054	1 478	797	507	238	549	18 739

Comment on Table 2:

Breastfed infants:

A total of 13 reports have been received regarding children under the age of 12 who are being breastfed, but who have not been vaccinated. Various symptoms have been reported in the children concerned after the mother received a vaccine dose, including fever, nausea, anxiety, rash or cold. In most of the breastfed 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.

- Nine reports concern symptoms in the child after the mother received Vaxzevria (AstraZeneca)
- Four reports concern symptoms in the child after the mother received Comirnaty (BioNTech/Pfizer)

One of the reports is classified as serious due to the child being admitted to hospital. There is generally a low threshold for admitting young children to hospital. The child was recovering when the suspected adverse reactions were reported.

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.

Young people and adverse reaction reports

Experience has shown that adverse reactions are more commonly reported in younger adults than in older adults. This can be attributed to the fact that younger people have a stronger immune response and more noticeable common adverse reactions, or that reports are issued more frequently for younger people in order to clarify whether the reaction is an adverse reaction to the vaccine or not. Younger people also tend to be more likely to report adverse reactions themselves.

Reports classified as serious

So far, 3,023 reports of events which are classified as serious have been assessed. This accounts for 16 % 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 48 % 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.

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).

- blood clot in the lungs
- pericarditis

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

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
- persistent headache
- 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	1.dose	2. dose	1.dose	1.dose
Number of doses administered	3 461 044	2 653 698	536 571	970 721	141 862 ***	5 068
Total number of reports	7 887*		2 225*		8 660*	7*
Number of reports involving death	193**		11**		6**	0**
Serious reports other than death	1 813		470		548	3
Non-serious reports	5 881		1 744		8 106	4
	<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-registraton of doses</i></p>					

administered abroad. Post-registration of vaccines administered abroad may effect the number of doses administered for all the coronavirus vaccines.

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

The fact that a person dies soon after being vaccinated does not necessarily mean that there is a causal relationship. So far, 210 reports of deaths soon after vaccination have been reported. Most deaths have occurred amongst elderly persons receiving nursing care and residents of nursing homes.

Nine reports concern deaths in fully vaccinated persons who have been diagnosed as having COVID-19. These cases are discussed in more detail in the section on breakthrough infection.

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 received 12 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 concerning thrombosis with thrombocytopenia syndrome (TTS)

In mid-March, cases were reported of a very rare but serious clinical picture involving a combination of blood clots, low blood platelet count and bleeding after vaccination with Vaxzevria. This is now referred to as thrombosis with thrombocytopenia syndrome (TTS) or vaccine-induced immune thrombotic thrombocytopenia (VITT). Vaxzevria is not used in the Norwegian vaccination programme.

Reports concerning TTS after vaccination with viral vector vaccine Vaxzevria (AstraZeneca):

- Seven confirmed cases of TTS/VITT after the Vaxzevria vaccine, four of which were fatal.
- One suspected case of TTS/VITT, which has not been confirmed.
- One case which does not meet the diagnostic criteria for TTS in accordance with the Brighton Collaboration.

No confirmed link has so far been demonstrated between the COVID-19 vaccines Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna) and the risk of VITT/TTS, but the European Medicines Agency (EMA) is closely monitoring the situation. As of 28 September 2021 there have been no reports that meet the diagnostic criteria for VITT/TTS after mRNA-vaccination.

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. Persons of all ages have been affected, but most cases of myocarditis have been reported in men under 30 years of age.

As of 28 September 2021, 161 cases of pericarditis and 90 cases of myocarditis have been reported in Norway after vaccination with mRNA-vaccine.

In addition there are 3 reports on pericarditis after vaccination with Vaxzevria.

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

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

Aldersgruppe								
	18-29	30-39	40-49	50-59	60-69	70-89	Ukjent alder	Total
Perikarditt	31	26	27	26	27	22	2	161
Myokarditt	47	10	11	7	9	5	1	90

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

	Kvinner	Menn
Perikarditt	55	106
Myokarditt	21	69

Reports of suspected adverse reactions in the 12 – 17 age group

We highly prioritise the assessment of reports in the 12 -17 age group. We are closely monitoring the situation and are particularly alert to reports of serious events following vaccination.

As of 28 September 2021, over 260,000 children and adolescents aged 12 to 17 had received at least one dose of vaccine. During the period December 2020 to 28 September 2021, we received and assessed 76 adverse reaction reports concerning this age group. 13 of these are classified as serious

Adolescents normally experience the same common and transient adverse reactions as adults following vaccination. Amongst the more rarely known adverse reactions are inflammation of the heart muscle (myocarditis) and inflammation of the heart lining (pericarditis). No reports of these adverse reactions have so far been received concerning this age group. Look out for symptoms such as chest pain, wheezing or rapid or irregular heart rate which particularly occurs during the first week after vaccination. Fever and cough may also occur.

Reports of breakthrough infection

No vaccine provides 100% protection against either infection or serious illness. The COVID-19 vaccines provide excellent protection against serious illness and death from COVID-19, as well as good protection against infection amongst those who have been fully vaccinated. The degree of protection may vary between the different vaccines. People may have a different immune response to the same vaccine, depending on their age and health. If a vaccinated person becomes seriously ill with COVID-19 more than 1-2 weeks after being fully vaccinated, this is considered to be a breakthrough infection and a possible case of vaccine failure.

As of 27 September 2021, we have assessed 32 reports from health professionals concerning poor or absent effects of the vaccine in fully vaccinated persons:

- Fifteen of the cases concerned fully vaccinated persons who were either asymptomatic or had mild/moderate symptoms of COVID-19
- Six cases where fully vaccinated persons were admitted to hospital with COVID-19. In one of the cases, the admission to hospital was reported as being due to a reason other than COVID-19
- Nine deaths with confirmed COVID-19
- In the case of two reports, no symptoms were described and they are not classifiable

The average age of the 32 fully vaccinated persons was 72. With the exception of one person who received a combination of Vaxzevria and Comirnaty, all persons had been vaccinated through two doses of Comirnaty, 3-6 weeks apart. The breakthrough infections occurred between just over two weeks and seven months after the last dose. Fewer than five reports of COVID-19 have been received concerning part-vaccinated persons. None of these became seriously ill.

Deaths in fully vaccinated persons with confirmed COVID-19

Nine deaths have been reported concerning fully vaccinated persons who had been confirmed as having COVID-19. The average age of those who died was 89 years, and six (67%) of these were stated as being very frail and having underlying conditions. The patients who died were diagnosed as having COVID-19 between two and seven months after vaccination, and the events were reported based on suspected vaccine failure.

It is not always possible to determine with any certainty whether patients died from or with COVID-19. A number of reports state that the death was probably due to a cause other than COVID-19, but it is not possible to rule out the possibility that the infection was a contributory factor. As regards the asymptomatic cases, COVID-19 is less likely to have been a contributory factor in the death

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:

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.

1. 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).

2. Health registers 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 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

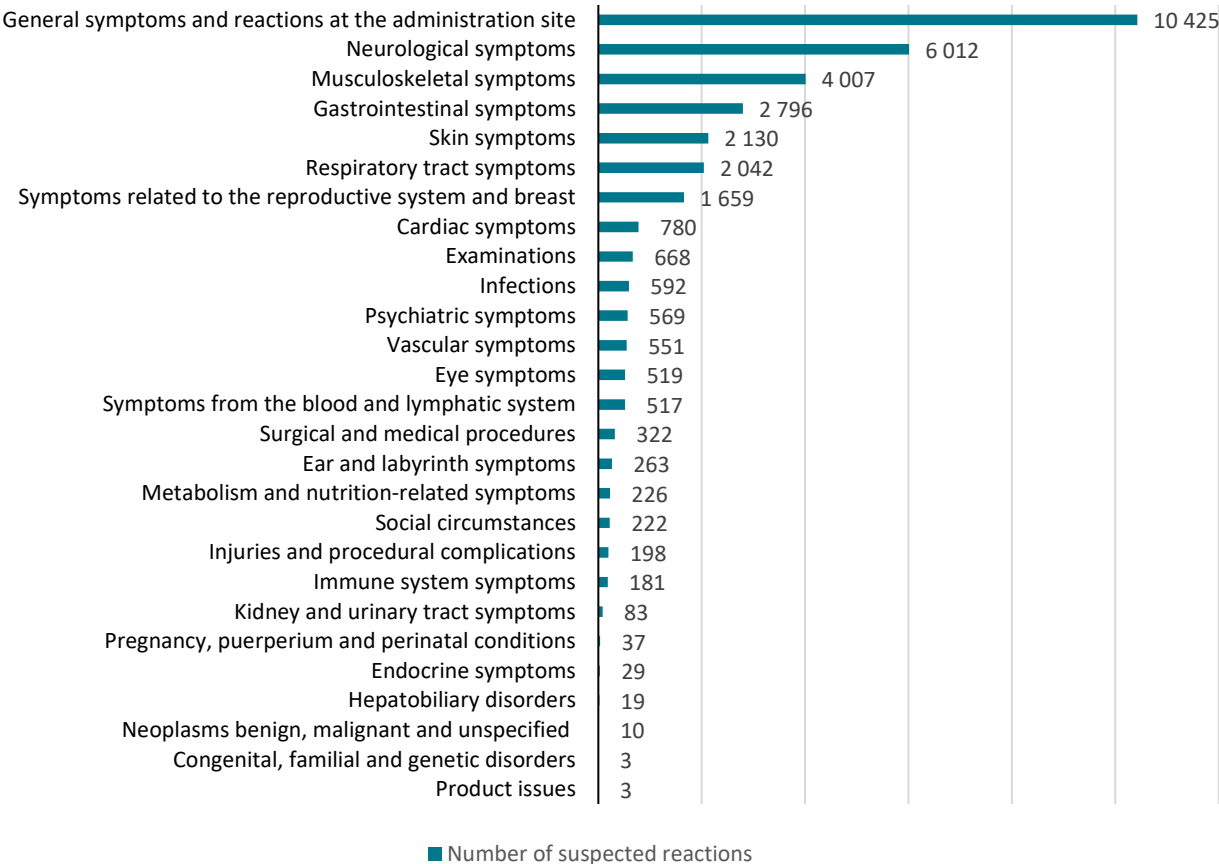


Table 6: Reported suspected adverse reactions by category for Comirnaty and Spikevax

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	10 425
Neurological symptoms E.g.: Headache, dizziness, drowsiness, syncope	6 012
Musculoskeletal symptoms E.g.: Muscle pain, joint pain, muscle stiffness, pain in the extremities	4 007
Gastrointestinal symptoms E.g.: Stomach pain, nausea, vomiting, diarrhoea	2 796
Skin symptoms E.g.: Rash, itching, redness, cold sweats	2 130
Respiratory tract symptoms E.g.: Difficulty breathing, shortness of breath, cough, irritation of the respiratory	2 042
Symptoms relating to the reproductive organs and breast E.g.: Breast pain and menstrual disorder	1 659
Cardiac symptoms E.g.: Bradycardia, tachycardia, pericarditis	780
Examinations E.g.: Abnormal and raised heart rate, decreased blood pressure, decrease in oxygen saturation	668
Infections E.g.: Pneumonia, cold symptoms	592
Psychiatric symptoms E.g.: Sleep abnormalities, restlessness, lethargy, hallucination	569
Vascular symptoms E.g.: Flushes, pallor, low blood pressure	551
Eye symptoms E.g.: Blurred vision, twitch	519
Symptoms from the blood and lymphatic system E.g.: Swollen lymph nodes	517
Surgical and medical procedures E.g.: Oxygen therapy, revaccination with other Covid-19 vaccine	322
Ear and labyrinth symptoms E.g.: Discomfort in the ear	263
Metabolic and nutrition-related symptoms E.g.: Reduced appetite	226
Social circumstances E.g.: Bedridden Immune system symptoms E.g.: Allergic reaction	222
Injuries and procedural complications E.g.: Fall	198
Immune system symptoms E.g.: Allergic reaction	181

Kidney and urinary tract symptoms E.g.: Urinary tract infection	83
Pregnancy, puerperium and perinatal conditions E.g.: Spontaneous abortion	37
Endocrine symptoms E.g.: Hypothyroidism	29
Hepatobiliary disorders E.g.: Portal vein thrombosis	21
Neoplasms benign, malignant and unspecified	10
Congenital, familial and genetic disorders	3
Product issues	3

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. However, the number of suspected adverse reactions to Vaxzevria will continue to rise, because a large number of reports have been received and there are non-serious reports which have yet to be assessed. It will take time to assess all the reports that have been received.

Many people have reported significant reactions after the first dose of Vaxzevria, and most reports concern known adverse reactions, such as reactions around the injection site, headache, fever, fatigue and deterioration in general condition.

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

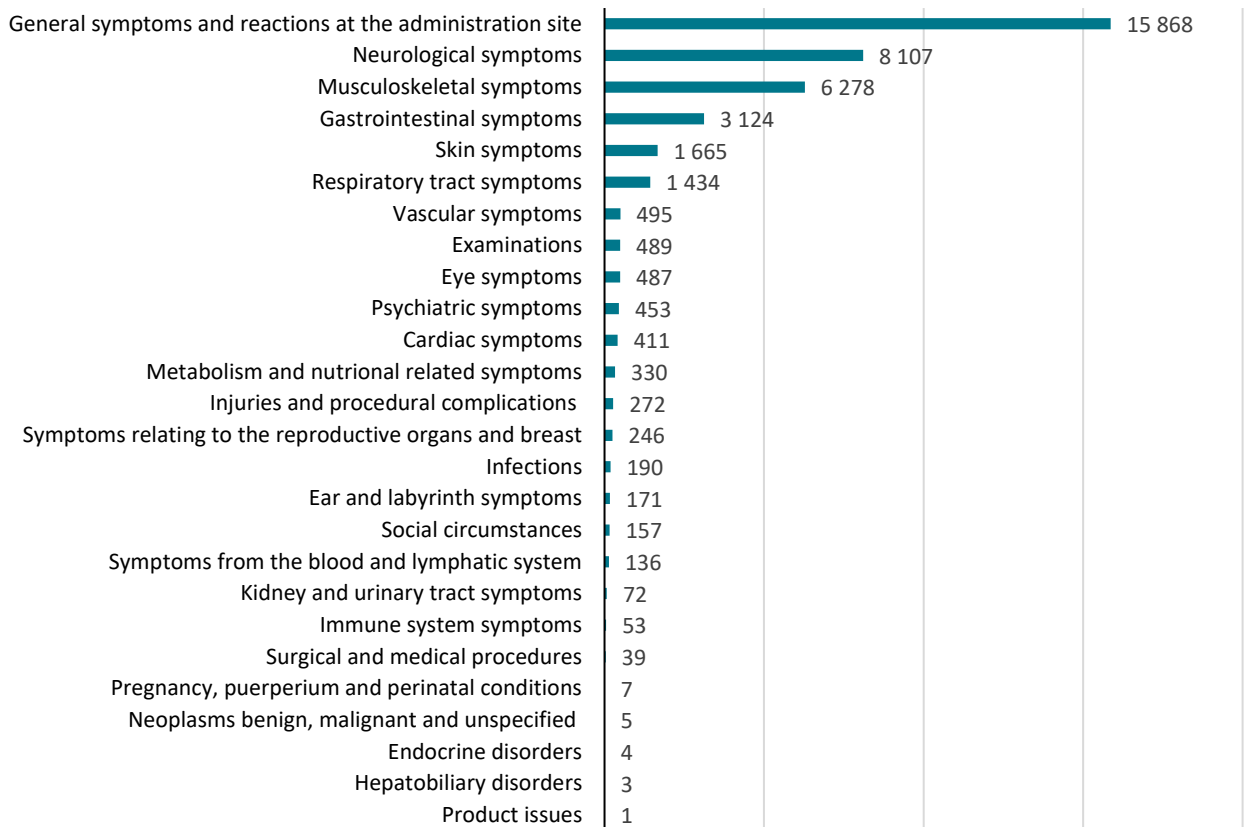


Table 7: Reported suspected adverse reactions by category for Vaxzevria and COVID-19 Vaccine Janssen

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	15 868
Neurological symptoms E.g.: Headache, dizziness, drowsiness, numbness	8 107
Musculoskeletal symptoms E.g.: Muscle pain, joint pain, back pain	6 278
Gastrointestinal symptoms E.g.: Stomach pain, nausea, vomiting, diarrhoea	3 124
Skin symptoms E.g.: Rash, skin pain, cold sweats	1 665

Respiratory tract symptoms E.g.: Difficulty breathing, hyperventilation, nasal congestion, pain and swelling of pharynx	1 434
Vascular symptoms E.g. Flushing	495
Examinations E.g.: Abnormal and raised heart rate	489
Eye symptoms E.g.: Blurred vision, twitch, eye pain	487
Psychiatric symptoms E.g.: Sleep abnormalities, insomnia	453
Cardiac symptoms E.g.: Palpitations	411
Metabolic and nutrition-related symptoms E.g.: Reduced appetite	330
Injuries and procedural complications E.g. Contusion	272
Symptoms relating to the reproductive organs and breast E.g. Pain in reproductive organs and nipples	246
Infections E.g. Sinus infection, cold symptoms	190
Ear and labyrinth symptoms E.g.: Discomfort in the ear, sound sensitivity	171
Social circumstances E.g.: Bedridden	157
Symptoms from the blood and lymphatic system E.g.: Swollen lymph nodes	136
Kidney and urinary tract symptoms E.g.: Frequent urination	72
Immune system symptoms E.g.: anaphylactic reaction, allergic reaction	53
Surgical and medical procedures E.g.: revaccination with different COVID-19 vaccine	39
Pregnancy, puerperium and perinatal conditions E.g.: spontaneous abortion	9
Neoplasms, benign, malignant and unspecified	5
Endocrine symptoms	4
Hepatobiliary disorders	3
Product issues	1