Norwegian
Medicines Agency

# Reported suspected adverse reactions to coronavirus vaccines

## About the report:

- A summary is presented below of all assessed reports concerning suspected adverse reactions following coronavirus vaccination from 27 December 2020, the date on which the first vaccine became available.
- The figures are taken from the Norwegian ADR Registry and include reports from healthcare professionals, the general population and Market Authorisation Holders in Norway.
- Only reports which have undergone quality assurance and been assessed in the Norwegian ADR Registry are included in the report. At any one time, there will be reports which are currently being assessed – these reports are not considered further in this summary.
- Reports of serious events are assessed first. The report therefore does not give a true picture of the distribution between serious and non-serious events.
- 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.
- This report contains all suspected adverse reactions regardless of any possible causal link.
- Additional information from the reporter or new knowledge concerning the vaccine may become available at any time which alters the assessment of the reports.
- The Norwegian Medicines Agency, the European Medicines Agency (EMA), the World Health Organization (WHO) and pharmaceutical companies review the reports of adverse reactions and perform statistical calculations in order to identify unknown adverse reactions (i.e. signal detection). When a signal is identified, a more thorough analysis is carried out to assess whether it could be a new adverse reaction to the drug, or whether any other factors more likely explain the signal. Based on these analyses, it may be appropriate to update the product information with new adverse reactions or introduce measures aimed at minimising the risks.
- Weekly reports are published which summarise the adverse reactions reported following vaccination with the coronavirus vaccines.

# Summary

**The ADR (adverse drug reaction) reports do not provide a basis for revising the current recommendations regarding the use of the coronavirus vaccines. The benefits of administering the vaccine are considered to outweigh any possible risks.**

There are currently no new indications of unexpected or serious adverse reactions in Norway. The suspected adverse reactions which have been observed following vaccination are generally in line with what is described in the product information.

Most reports concern transient adverse reactions, such as headache, fatigue, malaise, fever, nausea and body pain. These usually appear on the first or second day after vaccination and last around 2-3 days. Most people tolerate these transient adverse reactions well, while others experience significant discomfort during the first few days after vaccination.

Amongst the reports that have been assessed, there were reported 111 deaths with a temporal link to vaccination amongst elderly people in need of care, most of whom were nursing home residents. The average age in these cases is above 87 years. Several of the reporters state that no causal link to vaccination is suspected. The fact that a person dies soon after being vaccinated does not mean that there is a causal relationship. In order to analyse whether there could be a causal relationship, other data sources and advanced analyses are normally required.

In the case of some patients, there is always a possibility that relatively mild adverse reactions following the vaccination of frail elderly people contributed to a deterioration in their underlying illness.

# Coronavirus vaccines in use in Norway

Three coronavirus vaccines are approved for use in Norway:

- Comirnaty (BioNTech/Pfizer)
- COVID-19 Vaccine Moderna (Moderna)
- COVID-19 Vaccine AstraZeneca (AstraZeneca).

Comirnaty and COVID-19 Vaccine Moderna are mRNA vaccines, while COVID-19 Vaccine AstraZeneca is a virus vector vaccine. All are administered as two doses, a few weeks apart.

# Statistics concerning reports of suspected adverse reactions as of 2 March 2021

So far, a total of 3,636 reports of suspected adverse reactions following COVID-19 vaccination; of these, 1,822 have been assessed.

By 2 March 2021, over 344,000 people had received their first dose of COVID-19 vaccine, and over 166,000 people had received the second dose.

## Distribution of reports by gender

| Gender | Female | Male |
|---|---|---|
| Number | 1407 | 415 |

*Table 1: Gender breakdown amongst patients in the reports*

## Distribution of reports by age

| Age group | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **18-29** | **30-39** | **40-49** | **50-59** | **60-69** | **70-79** | **80-89** | **90+** | **Unknown age** |
| 305 | 454 | 321 | 194 | 60 | 82 | 215 | 171 | 20 |

*Table 2: Age distribution of patients in the reports*

The weekly report at FHI.no shows the number and proportion of persons vaccinated in different age groups and gender distribution nationwide.

## Distribution of reports according to severity for each vaccine

| Vaccine | Date adopted | Total number of reports | Number of reports involving death | Serious reports other than death | Reports of non-serious events |
|---|---|---|---|---|---|
| **Comirnaty (Pfizer/BioNTech)** | 27.12.2020 | 1371 | 110 | 124 | 1137 |
| **COVID-19 Vaccine Moderna (Moderna)** | 15.01.2021 | 57 | 1 | 6 | 50 |
| **COVID-19 Vaccine AstraZeneca (AstraZeneca)** | 08.02.2021 | 394 | 0 | 15 | 379 |

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

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

Reported events following vaccination are classified as serious when:

- *the event resulted in hospitalization/extended hospitalization*
- *the event is considered to be a medically important event*
- *the event resulted in a prolonged reduction in function level*
- *the event resulted in a life-threatening illness (e.g. anaphylaxis) or death*
- *the event resulted in birth defects/congenital malformations*

## Reports on deaths

So far, 111 reports of deaths after vaccination have been assessed concerning elderly patients in need of care, most of whom were nursing home residents. Many people in this patient group who have so far been vaccinated are very frail or terminally ill patients. At this time of year, an average of around 50 people die every day in the age group 85 years or older, and around 35 people every day in the age group 75-85. It is therefore to be expected that deaths will in time relation after vaccination, without there necessarily being any causal link to the vaccine. The reported deaths have occurred within a period of up to 3 weeks following vaccination.

The reporters of several of these fatal cases state that no link with vaccination is suspected, and that the death is being reported for the sake of completeness. Many of the patients were also very frail prior to vaccination, and had many concomitant medical conditions and were taking many different medicines. Amongst this patient group, a number of factors often contribute to death, and the actual cause of death can be difficult to establish. It can be difficult to know whether the death was caused by the patient's underlying condition or another incidental, concomitant event. In the case of some of the frailest patients, there is always a possibility that relatively mild adverse reactions to the vaccine could have contributed to a serious course of their underlying illness.

These reports do not currently constitute a signal of an adverse reaction and do not provide a basis for revising the product information for the vaccines.

The Norwegian Medicines Agency has set up an external group of geriatricians to look into these incidents in order to give us a better insight into any causal relationships.

## 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.

## Reactions to mRNA vaccines

- Comirnaty (Pfizer/BioNTech)
- COVID-19 Vaccine Moderna (Moderna)

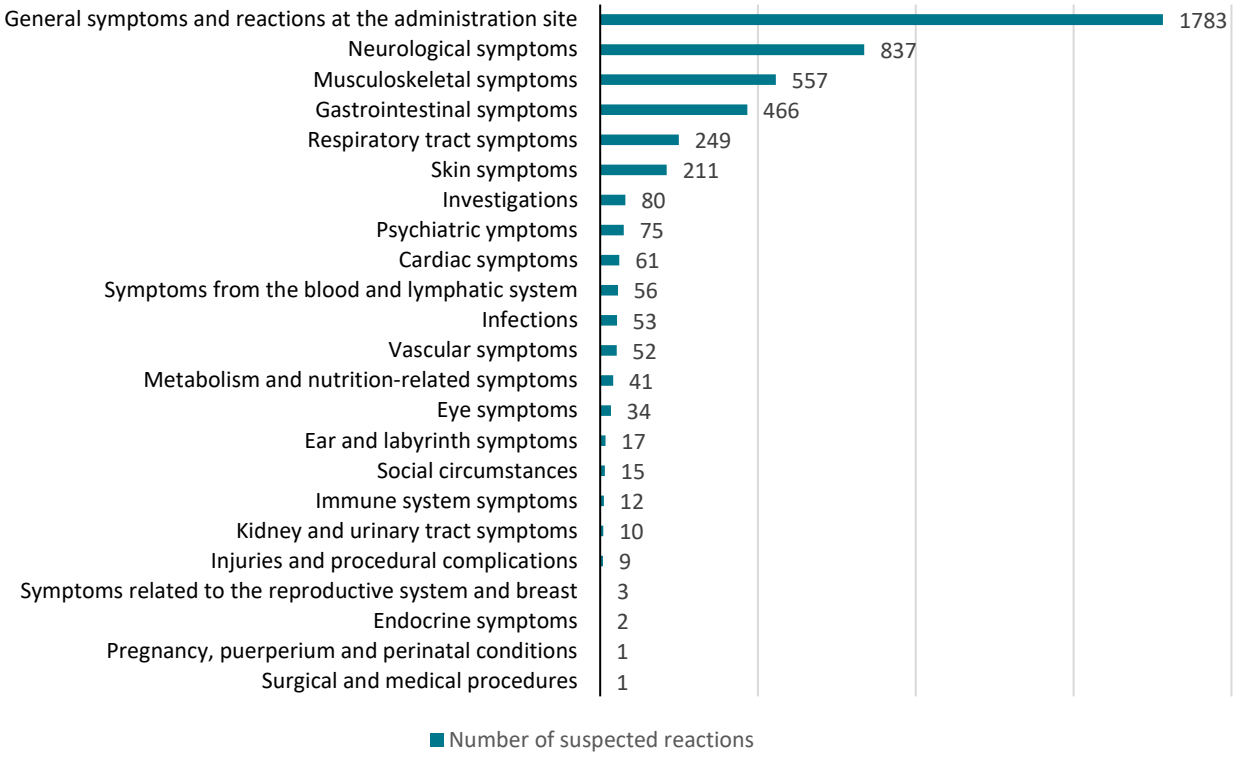


*Figure 1: Reported suspected adverse reactions by category for mRNA vaccines (Comirnaty and COVID-19 Vaccine Moderna)*

| Kategori | Number of suspected reactions |
|---|---|
| **General symptoms and reactions at the vaccine administration site**<br>E.g.: Pain and reactions at the injection site, discomfort, fever, fatigue, decreased general condition | 1783 |
| **Neurological symptoms**<br>E.g.: Headache, dizziness, drowsiness, syncope | 837 |
| **Musculoskeletal symptoms**<br>E.g.: Muscle pain, joint pain, muscle stiffness, pain in the extremities | 557 |
| **Gastrointestinal symptoms**<br>E.g.: Stomach pain, nausea, vomiting, diarrhoea | 466 |
| **Respiratory tract symptoms**<br>E.g.: Difficulty breathing, shortness of breath, cough, irritation of the respiratory | 249 |
| **Skin symptoms**<br>E.g.: Rash, itching, redness, cold sweats | 211 |
| **Examinations**<br>E.g.: Abnormal and raised heart rate, decreased blood pressure, decrease in oxygen saturation | 80 |

| | |
|---|---|
| **Psychiatric symptoms**<br>E.g.: Sleep abnormalities, restlessness, lethargy, hallucination | 75 |
| **Cardiac symptoms**<br>E.g.: Bradycardia, tachycardia | 61 |
| **Symptoms from the blood and lymphatic system**<br>E.g.: Swollen lymph nodes | 56 |
| **Vascular symptoms**<br>E.g.: Flushes, pallor, low blood pressure | 53 |
| **Infections**<br>E.g.: Pneumonia, cold symptoms | 52 |
| **Metabolic and nutrition-related symptoms**<br>E.g.: Reduced appetite | 41 |
| **Eye symptoms**<br>E.g.: Blurred vision, twitch | 34 |
| **Ear and labyrinth symptoms**<br>E.g.: Discomfort in the ear | 17 |
| **Social circumstances**<br>E.g.: Bedridden | 15 |
| **Kidney and urinary tract symptoms**<br>E.g.: Urinary tract infection | 12 |
| **Injuries and procedural complications**<br>E.g.: Fall | 10 |
| **Immune system symptoms**<br>E.g.: Allergic reaction | 9 |
| **Symptoms relating to the reproductive organs and breast** | 3 |
| **Endokrine symptomer** | 2 |
| **Pregnancy, puerperium and perinatal conditions** | 1 |
| **Surgical and medical procedures** | 1 |

*Table 4: Reported suspected adverse reactions by category for mRNA vaccines (Comirnaty and COVID-19 Vaccine Moderna)*

The most frequently reported symptoms 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 reported, as well as gastrointestinal symptoms such as diarrhoea, nausea and vomiting. The symptoms have arisen within 1-2 days after vaccination and have generally disappeared within a few days. Some reports have been received where the patient has developed infections such as pneumonia and influenza. As the mRNA vaccines are not live, they cannot cause conditions which are being vaccinated against or other infections

### Severe allergic reactions following vaccination with the mRNA vaccine

Seven serious allergic reactions have been reported following vaccination with Comirnaty. Severe allergic reactions are generally very rare and occur in 1-2 per million people who have been vaccinated with other vaccines. The incidence of anaphylactic reactions after vaccination with an mRNA vaccine appears to be higher than for other vaccines.

### Reports of higher blood sugar levels

Seven reports have been received where diabetic patients have developed higher blood sugar levels (hyperglycaemia) or experienced difficulty regulating their blood sugar levels during the first few days after being vaccinated with Comirnaty. Infectious diseases and fever are known to increase the risk of high blood sugar levels. It is possible that the common adverse reactions following vaccination, such as fever and nausea, could affect blood sugar levels.

### More pronounced reactions after the second dose of mRNA-vaccine than after the first

We are receiving reports of common adverse reactions following the second dose of mRNA vaccine. A number of these reports concern similar reactions following the first dose and indicate that the reactions were more severe following the second dose. This is described in the product information for the mRNA vaccines and in line with what was observed during the studies.

## Reactions to viral vector vaccines

- COVID-19 Vaccine AstraZeneca (AstraZeneca)

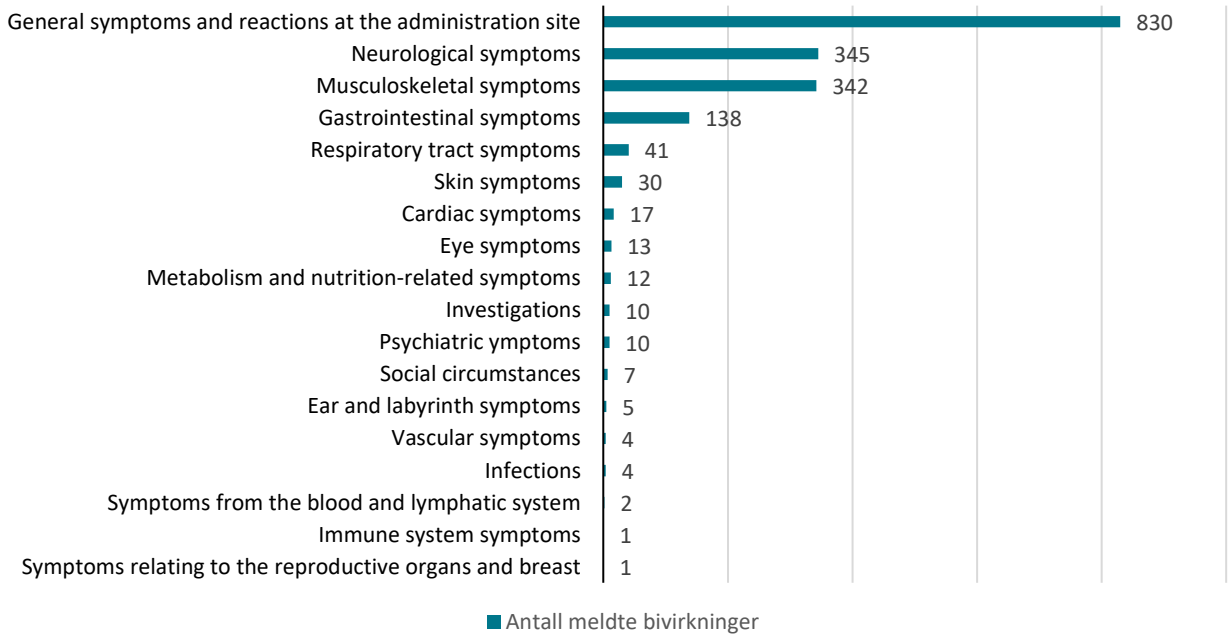


*Figure 2: Reported suspected adverse reactions by category for viral vector vaccines (COVID-19 Vaccine AstraZeneca)*

| Kategori | Antall meldte bivirkninger |
|---|---|
| **General symptoms and reactions at the vaccine administration site**<br>E.g.: Pain and reactions at the injection site, discomfort, fever, fatigue, decreased general condition | 830 |
| **Neurological symptoms**<br>E.g.: Headache, dizziness, drowsiness, numbness | 345 |
| **Musculoskeletal symptoms**<br>E.g.: Muscle pain, joint pain, back pain | 342 |
| **Gastrointestinal symptoms**<br>E.g.: Stomach pain, nausea, vomiting, diarrhoea | 138 |
| **Respiratory tract symptoms**<br>E.g.: Difficulty breathing, hyperventilation, nasal congestion, pain and swelling of pharynx | 41 |
| **Skin symptoms**<br>E.g.: Rash, skin pain, cold sweats | 30 |
| **Cardiac symptoms**<br>E.g.: Palpitations | 17 |
| **Eye symptoms**<br>E.g.: Blurred vision, twitch | 13 |
| **Metabolic and nutrition-related symptoms**<br>E.g.: Reduced appetite | 12 |
| **Examinations**<br>E.g.: Abnormal and raised heart rate | 10 |
| **Psychiatric symptoms**<br>E.g.: Sleep abnormalities, insomnia | 10 |
| **Social circumstances**<br>E.g.: Bedridden | 7 |
| **Ear and labyrinth symptoms**<br>E.g.: Discomfort in the ear | 5 |
| **Vascular symptoms** | 4 |
| **Infections** | 4 |
| **Symptoms from the blood and lymphatic system** | 2 |
| **Immune system symptoms** | 1 |
| **Symptoms relating to the reproductive organs and breast** | 1 |

*Table 4: Reported suspected adverse reactions by category for viral vector vaccines (COVID-19 Vaccine AstraZeneca)*

Suspected adverse reactions reported following vaccination with viral vector vaccines reflect the reactions observed during the studies and described in the summary of product characteristics for the AstraZeneca vaccine. Many people experience severe reactions after the first dose, but only minor reactions after the second, and most

reports concern known adverse reactions, such as reactions around the injection site, headache, fever, fatigue and deterioration in general condition.