



EXPLANATORY SHEET

Vaccination with an mRNA vaccine against COVID-19: Important information for patients

✓ You are being vaccinated against COVID-19

This information sheet is intended to supplement the vaccination discussion with a professional. Please read this information sheet carefully before the COVID-19 vaccination and discuss any questions you have with a professional at the vaccination centre.

General information on the COVID-19 vaccination

- We recommend vaccination against COVID-19 with an mRNA vaccine for everyone aged 12 and over.
- Two shots are usually required in the upper arm. You can have the second vaccination around four weeks after the first.
- If you are fully vaccinated with an mRNA vaccine, you have a much lower risk of contracting COVID-19 than if you are not vaccinated. The vaccination does not, however, provide absolute protection. If you do contract COVID-19 despite having been vaccinated, the illness should be less severe, and you should have fewer symptoms.
- According to the latest research, protection from becoming seriously ill probably lasts at least twelve months. There are presently no signs that protection from severe disease in the population at large declines after that.
- A booster vaccination is recommended for specific groups from at least six months after the primary vaccination course (see p.3). Experts are evaluating on an ongoing basis whether and when a booster vaccination should be recommended for the wider population.
- Once you have been fully vaccinated, the likelihood of becoming infected is greatly reduced, as is the risk of transmitting the virus. However, the vaccination does not provide 100% protection.
- The vaccine does not contain any coronaviruses and cannot trigger COVID-19. It cannot change human DNA.
- Vaccination before or during pregnancy protects the woman and the unborn child.
- In people with an immune deficiency (due to an illness or therapy), the vaccination may be less effective. If you have a weakened immune system, please seek advice from the specialist doctor treating you.
- Young people who are capable of judgement (even if they are under 18) are in principle entitled to decide whether they want to be vaccinated.

What side effects can the vaccine have?

- If the vaccine does have side effects, these will normally be mild to moderate and only last a few days. As with other vaccinations, these are generally reactions at the injection site (especially pain, or also redness or swelling) or general symptoms (such as tiredness, headaches, muscle and joint pains, high temperature).
- In some cases (in fewer than 1 in 100 vaccinated people), patients may experience COVID arm, which is redness and swelling in the vaccinated arm that appears around a week after the vaccination. While the reaction is unpleasant, it is harmless. It goes away without treatment in a few days and does not have any longer-term effects.
- Severe allergic reactions to a component of the vaccine (such as to polyethylene glycol/PEG) are very rare (occurring in around 1 in 100,000 vaccinations) and generally occur a few minutes after the vaccination. Initial signs include shortness of breath, a drop in blood pressure or severe reactions at the injection site. Serious allergic reactions of this kind are generally easy to treat.
Recommendation: Stay at the vaccination centre for at least 15 minutes after the vaccination.
- In very rare cases, predominantly among young men, inflammation of the heart muscle or the pericardium has been observed shortly after vaccination. A connection with the vaccination is currently deemed to be possible. The majority of these cases were mild and could be treated effectively. Typical symptoms of are chest pain, shortness of breath and palpitations.
- According to current research, the risk of suffering serious side effects after the vaccination is much lower than the risk of experiencing serious illness following infection with the coronavirus.
- At present, it is not possible to completely exclude the risk of rare severe side effects or unexpected side effects.



Experience acquired with other vaccines has shown that such events would be expected to occur within months of the vaccination. According to current research, the risk of this happening is, however, very low. The responsible agencies are closely monitoring possible indications. So far, no abnormalities have been found in the vaccination studies that have already been running for over a year involving tens of thousands of people, or in the hundreds of millions of people vaccinated worldwide.

- Other health problems – unrelated to the vaccination – may continue to arise, sometimes directly after a vaccination. This does not mean that they are necessarily a consequence of the vaccination.

Important: Please report any unexpected or serious symptoms experienced after the COVID-19 vaccination to a doctor, a pharmacist or the vaccination centre.

You should not get vaccinated in the following case:

- If you know that you suffer from hypersensitivity to components of the vaccine – in particular to polyethylene glycol (PEG).

The vaccination is currently not yet recommended in the following cases:

- In children under 12

Insufficient data is currently available on the use of the vaccines for this group.

Caution is advised for the vaccination in the following cases:

- If you are currently ill and have a high temperature.
→ In this case, you should postpone the vaccination.
- If you have acute allergies or take blood-thinning medication.
→ In both cases, you should inform the professional at the vaccination centre so that they can take special precautions.
- If you had a severe allergic reaction after the first vaccine dose.
→ You should only be vaccinated a second time in exceptional cases. Please talk to your doctor about the next steps.

Vaccination before or during pregnancy:

- Are you trying to get pregnant? If so, you should get vaccinated as soon as possible. After the COVID-19 vaccination you do not have to wait any particular length of time before getting pregnant.
- Are you already pregnant and didn't get vaccinated before you got pregnant? If so, we recommend the vaccination from 12 weeks of pregnancy (i.e. from the 2nd trimester). In principle, it is also possible to get vaccinated at an earlier stage of pregnancy.

- If a vaccine is unknowingly administered in the first trimester, this is not a cause for concern. There are no known negative effects on the embryo and no increased risk of miscarriage. Some countries recommend it in the first weeks of pregnancy (UK, United States).

Vaccination after a confirmed coronavirus infection

- If you have already tested positive for coronavirus.
→ Vaccination is also recommended in this case to ensure optimal and long-lasting protection. If possible, get yourself vaccinated within three months of having been infected. From four weeks after a confirmed coronavirus infection, one dose is usually sufficient. It may be possible to forego the second dose. Exceptions apply for people at especially high risk. Please talk to your doctor. From a medical perspective, vaccination is possible as soon as symptoms have disappeared. If the interval between infection and vaccination is less than four weeks, two doses of vaccine are necessary.

Important information for after the vaccination

- Make sure you receive a vaccination certificate and keep it somewhere safe.
- Have you already been given your second vaccination appointment? You should have the second vaccination approximately four weeks after the first one. The same vaccine must be used for both vaccinations.
- The full protection of the vaccination will have been built up one to two weeks after the second dose.
- Continue to follow the hygiene and social distancing rules, and wear a mask where this is required. But: if you are fully vaccinated, you don't have to keep your distance from other fully vaccinated people in social settings. If you have been in close contact with someone who has tested positive, you do not need to quarantine. And you are also exempt from many public health measures at the border.
- Please report any severe or unexpected symptoms experienced after the COVID-19 vaccination to a doctor, pharmacist or the vaccination centre.

Are you experiencing COVID-19 symptoms despite having been vaccinated? Then get tested. The isolation rules also apply to vaccinated persons.

Do you have any questions? You should discuss these with the professional vaccinating you.

This fact sheet does not replace the vaccination discussion with a professional.



**✓ You are receiving a booster**

This page supplements the previous pages with specific information on the booster vaccination with an mRNA vaccine. The information on side effects and special precautions is the same as for the primary vaccination course and is therefore not repeated here.

The COVID-19 booster vaccination is authorised and recommended for the following people:

For optimal individual protection against severe disease and hospitalisation, a booster is recommended for:

- People aged 65 or over (in particular those aged 75 or over and people aged 65 or over with chronic diseases that put them at the highest risk¹ of getting a severe case of COVID-19);
- Residents and people being looked after in nursing homes, care homes and day care facilities for older people.

The booster vaccination is authorised and recommended for the following people under certain circumstances:

A booster is not recommended across the board for the following people, but can be recommended in individual cases on request, after the person and their doctor have carried out a joint risk-benefit analysis:

- People at especially high risk aged under 65 with chronic diseases that put them at the highest risk¹ of getting a severe case of COVID-19.

The booster vaccination is not authorised or recommended for the following people, but can be considered in individual cases:

In individual cases, the following people can receive a booster on request after they and their doctor have carried out a risk-benefit analysis:

- Healthcare professionals working in particularly exposed healthcare settings (e.g. COVID-19 wards, intensive care units, nursing homes or care homes).

Use of the vaccine outside the terms of its authorisation is known as 'off-label use'. This is not set out in the Therapeutic Products Act (TPA), but is generally permissible. Responsibility for off-label use lies with the professional administering the vaccine. As part of their duty of care, they are also responsible for providing the person being vaccinated with the correct information.

Timing of booster vaccination:

A booster can be administered starting six months after completing the primary vaccination course. Primary vaccination course means

- two doses of an mRNA vaccine; or
- confirmed coronavirus infection + one dose of an mRNA vaccine at least four weeks apart (irrespective of the order).

If a coronavirus infection was confirmed within six months of completing the primary vaccination course, a booster is recommended six months after this infection. If the completion of the primary vaccination course and infection are more than six months apart, the infection counts as a booster and no further vaccination is needed.

Vaccine and dose for booster vaccination;

In principle, the same vaccine should preferably be used for the booster as for the primary vaccination course. If this is not available, the other mRNA vaccine can be used. If different mRNA vaccines were used for the primary vaccination course, either of the vaccines can be administered for the booster.

For the Pfizer/BioNTech vaccine, the same dose is administered for the booster as for the primary vaccination course. For the Moderna vaccine, half a dose is administered for the booster.

Do you have any questions? You should discuss these with the professional vaccinating you.

This fact sheet does not replace the vaccination discussion with a professional.

¹ Table 2, p. 11 of the mRNA vaccination recommendation: *definitions of diseases for people with the highest-risk chronic illnesses*