



## EXPLANATORY SHEET

# Vaccination with the vector vaccine from Janssen: 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 the vector vaccine from Janssen for everyone aged 18 and over who cannot be vaccinated with an mRNA vaccine for medical reasons or who refuses to accept the mRNA vaccines.
- With the vaccination 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 nevertheless do contract COVID-19 despite being vaccinated, the illness should be less severe, and you should have fewer symptoms.
- For full primary vaccination a single vaccination is required as a shot in the upper arm.<sup>1</sup>
- For better protection, we recommend, if possible, that between 28 days to 4 months after vaccination you supplement the primary immunisation with a dose of an mRNA vaccine from Moderna or Pfizer/BioNTech.
- The protection from infection and mild and severe illness diminishes with time. For this reason a booster is recommended (see page 3).
- Janssen's vector vaccine uses a harmless virus as a means of transport (vector) to transmit important instructions about the pathogen to our cells.
- The vaccine does not contain any coronaviruses and cannot trigger COVID-19.
- According to the latest research, Janssen's vector vaccine cannot change human DNA.
- 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.

#### 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 headaches, tiredness, muscle and joint pain, a high temperature).

- Severe allergic reactions to a component of the vaccine are very rare 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 isolated cases, rare forms of thrombosis (especially cerebral vein or abdominal vein thrombosis as well as arterial thrombosis) in connection with a lack of blood platelets have been observed within the first three weeks after vaccination with the Janssen vector vaccine. These events following vaccination with Janssen's vector vaccine were serious but occurred very rarely (in between 1 and 8 in every 1 million people).

Recommendation: In the period from a few days to three weeks after the vaccination, contact your doctor immediately if

- you observe small punctate haemorrhages or bruising on your skin, especially outside the injection site.
- you experience symptoms such as shortness of breath, chest pain, swelling in your arms or legs, persistent abdominal pain, severe and persistent headaches, seizures, a change in your mood or blurred vision.

- 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, however, the risk of this happening is very low. The responsible agencies are closely monitoring possible indications. So far, no other abnormalities have been found in the vaccination studies that have already been running for over a year involving several thousand people, or in the hundreds of millions of people vaccinated worldwide.

<sup>1</sup> Certain recommendations deviate from the approval (referred to as recommended off-label use). Off-label use is generally permitted if the

recommendations take account the latest scientific evidence, and the patient is informed accordingly and has given their consent.



- Other health problems – unrelated to the vaccine – 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 with the vector vaccine from Janssen in the following cases:**

- If you know that you suffer from hypersensitivity to components of the vaccine.
- If you have had capillary leak syndrome (CLS).

**Vaccination with the vector vaccine from Janssen is not recommended in the following cases:**

- In young people and children under 18
  - In pregnant and breastfeeding women
- Insufficient data is currently available on the use of the vaccine for these groups.
- Individuals with a weakened immune system (due to an illness or therapy).

**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.

**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-standing protection.  
If possible, get yourself vaccinated within three months of having been infected.

**Important information for after the vaccination**

- Stay at the vaccination centre for at least 15 minutes after the vaccination.
- Make sure you receive a vaccination certificate and keep it somewhere safe.
- The full protection of the vaccination will have been built up around three weeks after the vaccination.
- Continue to follow the hygiene and social distancing rules, and wear a mask where this is required.

But: if you are fully vaccinated, you do not have to keep your distance from other fully vaccinated people at private gatherings. 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 unexpected or serious symptoms experienced after the COVID-19 vaccination to a doctor, a 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 who have tested positive.

**Have you 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 vaccination.

This page supplements the previous pages with specific information on the booster. The information on side effects and precautions is the same as for primary immunisation and is not repeated here.

#### What's the purpose of a booster vaccination?

The protection from infection and mild and severe illness diminishes with time. The booster vaccination reminds the immune system of the pathogen. Increased vaccine protection is restored and prolonged.

#### The booster vaccination or an additional vaccine dose is recommended for the following people:

The booster vaccination or an additional vaccine dose is recommended for anyone who has received their primary immunisation with the Janssen vaccine.

- Everyone is recommended to preferably have a booster with an mRNA vaccine from 4 months after primary immunisation with the Janssen vaccine.<sup>2</sup>
- People who cannot be vaccinated with an mRNA vaccine for medical reasons or who refuse mRNA vaccines are recommended to receive a second dose of Janssen's vaccine from 2 months after primary immunisation.<sup>3</sup>

The booster vaccination or an additional vaccine dose increases protection against severe COVID-19 illness requiring hospitalisation as well as against infections, mild illnesses and their consequences (e.g. long-term consequences of COVID-19, incapacity for work) and can temporarily reduce the spread of the virus.

#### Booster after a confirmed coronavirus infection

If an infection with coronavirus has been confirmed within 4 months after full primary immunisation, a booster vaccination with an mRNA vaccine or a second dose of Janssen's vaccine is recommended 4 months after this infection. However, if more than 4 months have elapsed between primary vaccination and the infection, this infection counts as a booster and, as a rule, no further vaccination is currently necessary.

**Do you have any further questions? You should discuss these with the professional vaccinating you. This fact sheet does not replace the vaccination discussion with a professional.**

<sup>2</sup> Certain recommendations deviate from the approval (referred to as recommended off-label use). Off-label use is generally permitted if the recommendations take account the latest scientific evidence, and the patient is informed accordingly and has given their consent.

<sup>3</sup> People who have had their primary immunisation with an mRNA vaccine can receive a booster with the Janssen vaccine after 4 months.

