

## INFORMATION SHEET

### For vaccination against COVID-19 (**Corona Virus Disease 2019**)

— with vector vaccine — as of 2 February 2021 (this information sheet is continually updated)

Name of the person to be vaccinated (please print):

Date of birth:

#### **What is COVID-19?**

Coronaviruses have been known for decades. As of the turn of the year 2019/2020, a novel coronavirus, SARS-Coronavirus-2 (SARS-CoV-2), which is the pathogen of COVID-19 (Corona Virus Disease 2019), has been circulating globally.

Frequent symptoms of COVID-19 include dry cough, fever, shortness of breath, as well as a temporary loss of smell and taste. A general feeling of being unwell accompanied by headaches and aching limbs, sore throat, and sniffles are also reported. Patients less often report having gastrointestinal problems, conjunctivitis, and swelling of the lymph nodes. Consequential damage to the nerves or cardiovascular system as well as persisting courses of the disease are possible. Although the disease often runs a mild course and most patients fully recover, severe courses of the disease involving pneumonia, which can result in death due to respiratory failure, are dreaded.

In addition to avoiding an infection by observing the AHA + A + L rules (maintaining social distance, observing hygiene, wearing a mask in day-to-day life, downloading the corona warning app, frequent ventilation of rooms), the vaccine offers the best possible illness protection.

#### **Which vaccine is involved?**

Currently, there are three vaccines approved against COVID-19 that are suitable for individual protection against COVID-19 and as a response to the pandemic. The COVID-19 vector vaccine discussed here (COVID-19 Vaccine AstraZeneca® from AstraZeneca) is a genetically engineered vaccine based on advanced technology. Vector vaccines against other diseases are already approved and have been shown to be tolerable and effective.

The vaccine consists of a well-studied virus that cannot replicate and is harmless to humans. This virus (also called a vector virus) contains and transports the genetic information for a single protein of the corona virus, the so-called spike protein. This spike protein is harmless in its own right.

The information transported by the vector virus is not integrated into the human genome after vaccination, but is "read" in cells (primarily in muscle cells at the vaccination site and in certain immune cells), whereupon such cells then produce the spike protein themselves. The spike proteins thus generated by the body of the vaccinated person are recognised as foreign proteins by the immune system; as a result, antibodies and immune cells are produced against the spike protein of the virus. This produces a protective immune response.

The vector virus cannot reproduce in the human body and decomposes after a short time. Thereafter, no additional virus protein (spike protein) is produced.

**How is the vaccine administered?**

Typically, the vaccine is injected into the upper arm muscle. The vaccine must be administered twice. For sufficient vaccination protection, the Standing Committee on Immunisation at the Robert Koch Institute (STIKO) recommends an interval of 9 to 12 weeks between the first and second vaccinations. For the second vaccination, the same vaccine from the same manufacturer must be used as for the first vaccination.

**How effective is the vaccine?**

The clinical trials of the AstraZeneca® COVID-19 vaccine seem to suggest vaccine protection starting on day 15 after the second vaccination. According to the STIKO recommendation, based on the current level of knowledge, the vaccine offers a good efficacy rate of approximately 70% in persons aged 18 to 64 years and with an interval of 9 to 12 weeks between the two vaccinations. The study data show that the probability of becoming infected with COVID-19 was approximately 70% lower for those vaccinated against COVID-19 than for those who were not vaccinated. This means that, if a person vaccinated with this COVID-19 vaccine comes into contact with the pathogen, there is a significant probability that the person will not become ill.

It is not yet known how long this vaccine protection lasts and whether vaccinated individuals can spread the virus. Because protection does not set in immediately after vaccination and is not present in equal measure in all vaccinated persons, it is necessary to protect yourself and your environment – even despite being vaccinated – by following the safety rules (social distancing, hygiene, wearing a facemask and ventilation of rooms).

**Who benefits in particular from the vaccine?**

The AstraZeneca® COVID-19 vaccine is currently approved for individuals 18 years of age and older. However, as initially a sufficient amount of the vaccine is not available for treating everyone, persons having either a particularly high risk for a serious or fatal course of COVID-19 (e.g. older persons), those at a particularly high risk of being infected with SARS-CoV-2 due to their profession or those having contact to persons particularly threatened by COVID-19 due to their profession, should be preferentially vaccinated. As there is currently insufficient experience on the efficacy rate of the AstraZeneca® COVID-19 vaccine in elderly persons, STIKO currently does not recommend vaccination with this vaccine for persons older than 64 years.

**Who should not be vaccinated?**

Children and adolescents under 18 years of age, for whom the AstraZeneca® COVID-19 vaccine is not approved, should not be vaccinated with COVID-19 vector vaccine. The STIKO currently does not recommend vaccination with the AstraZeneca® COVID-19 vaccine for persons over 64 years of age, because there is not yet sufficient experience on the efficacy rate from studies for this age group.

Those suffering with an acute illness accompanied by a fever (38.5 °C and higher) should only be vaccinated after recovery. However, a cold or slightly elevated temperature (below 38.5 °C) is no reason to postpone vaccination. Those with a hypersensitivity to a substance of a vaccine should not be vaccinated – please inform the practitioner administering the vaccine if you have allergies prior to being vaccinated. Any person who had an immediate allergic reaction (anaphylaxis) after the first vaccination should not receive the second vaccination.

Persons, in whom an infection in the last 6 months with the novel coronavirus was proven, should not be vaccinated for the time being. This also applies to persons in whom an infection occurred after the first vaccination. However, there is no evidence that vaccination poses a risk if one has had an infection in the past. Thus, there is no medical necessity to rule this out prior to vaccination.

No sufficient experience is yet available on the use of COVID-19 vector vaccine during pregnancy and breastfeeding. STIKO does not currently recommend general vaccination during pregnancy – regardless of the type of COVID-19 vaccine. In individual cases, pregnant women with pre-existing conditions who are at high risk for a severe course of COVID-19 disease may be offered vaccination after a risk-benefit assessment and detailed consultation. STIKO considers it unlikely that vaccination of the mother during breastfeeding poses a risk to the infant.

Prior to your vaccination, please inform your doctor if you have a coagulation disorder or are taking anticoagulant medication. You can be vaccinated with simple precautions. There is nothing to prevent vaccination in persons with immune deficiency. However, vaccination may not be as effective in such persons.

### **How should I behave prior to and after receiving the vaccine?**

If you have fainted following a previous vaccination or other injection or have a tendency towards immediate allergies, please inform the physician administering the vaccine accordingly. He/she can then potentially observe you for an extended period after vaccination.

An interval of at least 14 days from receiving other vaccines should be maintained.

You do not have to rest after receiving the vaccination. In the event of pain or fever after the vaccination (see “What types of reactions to the vaccine may occur after receiving the vaccine?”), analgesic/antipyretic medication (e.g. paracetamol) can be taken. You can consult with your family practitioner about this.

### **What types of reactions to the vaccine may occur after vaccination?**

Following vaccination with the COVID-19 vector vaccine, local and general reactions can occur as an expression of the interaction of the body with the vaccine.

AstraZeneca® COVID-19 vaccine: The most frequently reported vaccine reactions during the previous mostly two-month observation period were tenderness at the injection site (more than 60%), pain at the injection site, headache and fatigue (more than 50%), muscle pain and discomfort (more than 40%), elevated temperature and chills (more than 30%), joint pain and nausea (more than 20%). Frequently (between 1% and 10%), vomiting, diarrhoea, redness and swelling of the injection site along with fever have been reported. Occasionally (between 0.1% and 1%), lymph node swelling, reduced appetite, dizziness, drowsiness, increased sweating, itching and a general rash occurred.

In older persons, most of these reactions are observed somewhat less often than in younger persons. Vaccine reactions are mostly mild or moderate, usually last a few days and occur somewhat less frequently after the second vaccination than after the first vaccination.

**Are complications possible due to the vaccine?**

As with all vaccines, in very rare cases an immediate allergic reaction up to and including shock or other previously unknown complications cannot be categorically precluded.

If symptoms occur following a vaccination, which exceed the aforementioned quickly passing local and general reactions, your family practitioner is naturally available for consultation. In the event of severe impacts, please seek immediate medical attention.

There is also the option of reporting side effects yourself: <https://nebenwirkungen.bund.de>

**In addition to this information sheet, your practitioner administering the vaccine will provide you with the opportunity to have a clarification discussion.**

Annotations:

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Signature of the practitioner

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Signature of the person to receive the vaccine

or if the person to be vaccinated is not competent to provide consent:  
Signature of the legal representative  
(custodian, legal care provider or guardian)

The Paul Ehrlich Institute (PEI) is conducting a survey about the tolerability of the vaccines for protecting against the novel coronavirus (SARS-CoV-2) by means of the SafeVac 2.0 smart phone app. The survey is voluntary.



Google Play App Store    App Store Apple

You can find additional information about COVID-19 and about the COVID-19 vaccine at

[www.corona-schutzimpfung.de](http://www.corona-schutzimpfung.de)  
[www.infektionsschutz.de](http://www.infektionsschutz.de)  
[www.rki.de/covid-19-impfen](http://www.rki.de/covid-19-impfen)  
[www.pei.de/coronavirus](http://www.pei.de/coronavirus)

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in Kooperation mit



## Medical history for preventive vaccination against COVID-19 (Coronavirus Disease 2019) – with vector vaccine

**1. Do you<sup>1</sup> currently have an acute illness with fever?**

☐ Yes

☐ No

**2. In the event you<sup>1</sup> have already received the first COVID-19 vaccine dose: Did you<sup>1</sup> develop an allergic reaction thereafter?**

☐ Yes

☐ No

**3. Do you<sup>1</sup> suffer from chronic diseases or immunodeficiency (e.g. due to chemotherapy, immunosuppressive therapy or other medications)?**

☐ Yes

☐ No

If yes, which

**4. Do you<sup>1</sup> suffer from a coagulation disorder or do you take blood-thinning medication?**

☐ Yes

☐ No

**5. Do you<sup>1</sup> have any known allergies?**

☐ Yes

☐ No

If yes, which

**6. Did you<sup>1</sup> experience any allergic symptoms, high fever, fainting spells or other uncommon reactions following a previous different vaccination?**

☐ Yes

☐ No

If yes, which

**7. For women of a childbearing age: Are you currently pregnant or nursing<sup>1</sup>?**

☐ Yes

☐ No

**8. Have you<sup>1</sup> been vaccinated within the last 14 days? \_\_\_\_\_**

☐ Yes

☐ No

**9. Have you<sup>1</sup> already received a vaccination against COVID-19?**

☐ Yes

☐ No

If yes, when and with which vaccine: Date:

Vaccine:

*(Please bring your vaccination card or other proof of vaccination to your vaccination appointment.)*

<sup>1</sup> This will be answered by the legal representative, if applicable.

## Declaration of Consent for preventive vaccination against COVID-19 (Coronavirus Disease 2019) – with vector vaccine

Name of the person to be vaccinated (surname, first name):

Date of birth:

Address:

If the person to be vaccinated is not competent to provide consent, consent to vaccination or refusal of vaccination will be given by the legal representative. In such a case, please also provide the name and contact details of the legal representative:

Surname, first name:

Telephone no.:

E-mail:

I have taken note of the contents of the information sheet and had the opportunity to have a detailed discussion with my practitioner administering the vaccine.

- ☐ I have no further questions.
- ☐ I consent to the recommended vaccine against COVID-19 with vector vaccine.
- ☐ I refuse the vaccine.
- ☐ I expressly renounce the medical clarification discussion.

Annotations:

Place, date:

Signature of the person to receive the vaccine  
or if the person to be vaccinated is not competent  
to provide consent:

Signature of the legal representative (custodian,  
legal care provider or guardian)

Signature of the practitioner

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