INFORMATION SHEET

For vaccination against COVID-19 (**Co**rona **Vi**rus **D**isease 20**19**)

– with vector vaccine – (Vaxzevria®, formerly AstraZeneca COVID-19 vaccine from AstraZeneca and Janssen® COVID-19 vaccine from Johnson & Johnson)

as of 1 April 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 has also been 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 for example with pneumonia, do occur as well and may result in death.

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?

Multiple vaccines have been approved against COVID-19, which are equally suitable for individual protection against COVID-19 and as a response to the pandemic. The COVID-19 vector vaccines discussed here (Vaxzevria® from AstraZeneca, formerly AstraZeneca® COVID-19 vaccine) and Janssen® COVID-19 vaccine from Johnson & Johnson) are gene-based vaccines, the production of which is predicated on advanced technology. Vector vaccines against other diseases are already approved.

The vaccines consist of so-called vector viruses. The vector virus in question is a well-studied virus that cannot replicate. They are not live vaccines. The vector virus contains and transports the genetic information for a single protein of the corona virus, the so-called spike protein. The COVID-19 vector vaccines do not contain replicable vaccine viruses, which means that vaccinated persons cannot transmit vaccine viruses to other persons.

The information transported by the vector virus is not integrated into the human genome after vaccination, but after entry 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

protein by itself cannot cause SARS-CoV-2 infection. 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?

The vaccine is injected into the upper arm muscle. Vaxzevria® from AstraZeneca 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. At the present time, for the second vaccination, the same vaccine from the same manufacturer must be used as for the first vaccination; an exception applies to persons under 60 years of age for whom Vaxzevria® from AstraZeneca was used for the 1st vaccination. For such persons, STIKO currently recommends that the 2nd vaccination be carried out 12 weeks after the 1st vaccination with an mRNA vaccine (Comirnaty® from BioNTech/Pfizer or Moderna® COVID-19 vaccine from Moderna).

Janssen® COVID-19 vaccine from Johnson & Johnson only needs to be administered once.

How effective is the vaccine?

Based on the current level of knowledge, both COVID-19 vector vaccines offer good efficacy: AstraZeneca's Vaxzevria® showed up to 80% efficacy in all age groups when the interval of 12 weeks between both vaccinations as recommended by STIKO was observed, and Johnson & Johnson's Janssen® COVID-19 vaccine showed efficacy of approximately 65%. This means that the probability of becoming infected with COVID-19 was up to 80% (Vaxzevria® from AstraZeneca) or approximately 65% (Janssen® COVID-19 vaccine from Johnson & Johnson) among persons vaccinated against COVID-19) lower than those non-vaccinated. Efficacy with respect to the prevention of serious COVID-19 illness (e.g. treatment at hospital) was even higher: approximately 95% with COVID-19 Vaxzevria® from AstraZeneca and approximately 100% with Janssen® COVID-19 vaccine from Johnson & Johnson. Thus, 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. How long this vaccine protection lasts is currently unknown.

Even if you are vaccinated, it is necessary that you continue to observe the AHA + A + L rules and thus protect yourself and your surroundings. The reasons for this are that protection does not start immediately after vaccination, and is also not equally present in all persons who were vaccinated. In addition, whether persons can spread the virus (SARS-CoV-2) despite being vaccinated is currently not possible to say with certainty.

Who benefits in particular from a vaccine against COVID-19?

Several vaccines against COVID-19 are approved and are equally suitable for individual protection against COVID-19 and pandemic response. As long as 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, 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.

Who should not be vaccinated?

Since COVID 19 vector vaccines are not approved for children and adolescents up to and including 17 years of age, they should not be vaccinated with COVID 19 vector vaccines.

STIKO recommends vaccination with AstraZeneca's Vaxzevria® only for persons 60 years of age or older. For adults below this age limit, STIKO does not currently recommend vaccination with this vaccine, as serious illnesses have occurred in some rare cases, predominantly in people under 60 years of age. Such illnesses included blood clots (thromboses) in combination with a reduction in the blood platelet count (thrombocytopenia) and were sometimes accompanied by bleeding. Some of these persons have died.

For individuals 60 years of age and older, the risk of becoming severely ill with COVID-19 or dying from COVID-19 is significantly higher than for younger individuals. In addition, the complications described above occurred quite predominantly in persons younger than 60 years. Vaccination with Vaxzevria® from AstraZeneca® is therefore recommended for persons 60 years and older. The vaccine has been shown to have good efficacy in this age group as well.

According to the STIKO recommendation, vaccination with Vaxzevria® from AstraZeneca is still possible in people under 60 years of age if they make this decision together with their doctor.

The second vaccination following the initial vaccination with Vaxzevria® from AstraZeneca:
For persons 60 years of age and older who received their 1st vaccination with AstraZeneca's Vaxzevria®, it is recommended that they also receive their 2nd vaccination with AstraZeneca's Vaxzevria®.
For individuals under 60 years of age who have already been vaccinated with AstraZeneca's Vaxzevria®, STIKO currently recommends that the 2nd vaccination be given 12 weeks after the 1st vaccination with an mRNA vaccine (Comirnaty® from BioNTech/Pfizer or Moderna® COVID-19 vaccine from Moderna).

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 with no immunodeficiency, in whom an infection with the novel coronavirus was positively proven, can be vaccinated no sooner than 6 months after recovery or after the diagnosis and should only receive one dose of the vaccine. Currently, it cannot be stated whether or not a subsequent 2nd dose is necessary for these persons. Persons, in whom an infection with the novel coronavirus following the first vaccination was positively proven can receive the 2nd vaccine no sooner than 6 months after the infection according to the STIKO recommendation. 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 the COVID-19 vector vaccines 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 highly 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.

Please also tell the doctor prior to vaccination if you have allergies or have had an allergic reaction after a vaccination in the past. The doctor will clarify with you whether there is any reason not to have the vaccination.

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 can be taken. You can consult with your family practitioner about this.

Seek immediate medical attention if, after vaccination, you develop shortness of breath, chest pain, swelling of the legs or persistent abdominal pain.

You should also see a doctor immediately if you have severe or persistent headaches or blurred vision after vaccination, or if you develop bruises or petechiae outside the injection site after a few days.

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

Following vaccination with the COVID-19 vector vaccines, short-term and temporary local and general reactions can occur as an expression of the interaction of the body with the vaccine. These reactions may include fever, chills, and other flu-like symptoms. They usually subside within a few days following vaccination. To alleviate potential symptoms, an analgesic/antipyretic medication can be taken in the recommended dosage.

Vaxzevria® von AstraZeneca®: The most frequently reported vaccine reactions during the approval studies 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.

Janssen® COVID-19 vaccine by Johnson & Johnson: The most commonly reported vaccine reactions in the approval studies were pain at the injection site (more than 40%), headache, fatigue and muscle

pain (more than 30%), and nausea (more than 10%). Frequently (between 1% and 10%), fever, cough, joint pain, redness and swelling of the injection site along with chills were reported. Occasionally (between 0.1% and 1%), tremors, sneezing, pain in the mouth and throat, general rash, increased sweating, weakness of muscles, pain in the arm or leg, back pain, general feeling of weakness, and malaise occurred.

In older persons, most of these reactions are observed somewhat less often than in younger persons. Vaccine reactions are mostly mild or moderate and with Vaxzevria® from AstraZeneca occur somewhat less frequently after the second vaccination than after the first vaccination.

Are complications possible due to the vaccine?

Complications due to the vaccine are effects of the vaccine that exceed the normal extent of a vaccine reaction, which significantly affect the health condition of the vaccinated person.

Vaxzevria® von AstraZeneca: Since the introduction of the vaccine, blood clots (thrombosis) associated with a reduction in the platelet count (thrombocytopenia), sometimes accompanied by bleeding, have been observed in very rare cases following vaccination with Vaxzevria® from AstraZeneca®. These included some severe cases involving blood clots in different or unusual locations (e.g. cerebral venous sinus thromboses or in the abdominal cavity as mesenteric vein thrombosis), along with increased blood clotting activity or even bleeding throughout the body. The majority of these cases occurred between four to 16 days after vaccination and predominantly in persons below the age of 60. Some of the cases described ended fatally or with permanent damage.

Janssen® COVID-19 vaccine from Johnson & Johnson: In rare cases (0.01% to 0.1%), hypersensitivity reactions and hives occurred.

Since introducing the vaccine, immediate allergic reactions (anaphylactic reactions) were reported in very rare cases. They occurred shortly after vaccination and required medical treatment. 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, especially shortness of breath, chest pain, leg swelling or persistent abdominal pain, severe or persistent headache or visual disturbances, or if you experience bruising or pinpoint bleeding of the skin outside the injection site a few days after vaccination, please seek medical attention immediately.

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:

Signature of the practitioner

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. You can register within 48 hours after vaccination. 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
www.infektionsschutz.de
www.rki.de/covid-19-impfen
www.pei.de/coronavirus

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in Kooperation mit

ROBERT KOCH INSTITUT

Medical history for preventive vaccination against COVID-19 (Coronavirus Disease 2019) – with vector vaccine - (Vaxzevria®, formerly AstraZeneca COVID-19 vaccine from AstraZeneca and Janssen® COVID-19 vaccine from Johnson & Johnson)

1. Do you[1] currently have an acute illness with fever?

0 Yes 0 No

2. Have you[1] already receive a vaccination against COVID-19?

0 Yes 0 No

If yes, when and with which vaccine? Date: Vaccine:

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

3. In the event you[1] have already received the first COVID-19 vaccine dose: Did you[1] develop an allergic reaction thereafter?

0 Yes 0 No

4. Has it been reliably proven that you[1] were infected with the novel coronavirus (SARS-CoV-2) in the past? *(After infection with SARS-CoV-2, vaccination is recommended no earlier than 6 months after recovery or diagnosis.)*

0 Yes 0 No

If yes, when?

5 Do you[1] have chronic diseases or do you[1] suffer from immunodeficiency (e.g. due to chemotherapy, immunosuppressive therapy or other medications)?

0 Yes 0 No

If yes, which

6. Do you[1] suffer from a coagulation disorder or do you take blood-thinning medication?

0 Yes 0 No

7. Do you[1] have any known allergies?

0 Yes 0 No

If yes, which

8. Did you[1] experience any allergic symptoms, high fever, fainting spells or other uncommon reactions following a previous different vaccination?

0 Yes 0 No

If yes, which

9. For women of a childbearing age: Are you currently pregnant or nursing[1]?

0 Yes 0 No

10. Have you[1] been vaccinated within the last 14 days? _____

0 Yes 0 No

[1] This will be answered by the legal representative, if applicable.

Declaration of Consent for preventive vaccination against COVID-19

– with vector vaccine – (Vaxzevria®, formerly AstraZeneca COVID-19 vaccine from AstraZeneca and Janssen® COVID-19 vaccine from Johnson & Johnson)

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.

- o I have no further questions.
- o I consent to the recommended vaccine against COVID-19 with vector vaccine.
- o I refuse the vaccine.
- o 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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