INFORMATION SHEET

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

– with mRNA vaccines – (Comirnaty® from BioNTech/Pfizer and

COVID-19 Vaccine Moderna® from Moderna)

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 are also depicted. 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, masking in day to day life, downloading the corona warning app, frequent ventilation), the vaccine offers the best possible illness protection.

Which vaccine is involved?

Several vaccines against COVID-19 are approved and are equally suitable for individual protection against COVID-19 and pandemic response. The mRNA COVID-19 vaccines discussed here (BioNTech/Pfizer's Comirnaty® and Moderna's COVID-19 Vaccine Moderna®) are gene-based vaccines that are predicated on the same new type of technology. Additional mRNA vaccines are being tested, although they have not yet been approved.

mRNA (messenger RNA or ribonucleic acid) is the “blueprint” for each individual protein of the body and must not be confused with human genetic information – DNA. A “blueprint” for a single element of the virus (the so-called spike protein) is contained in the mRNA vaccines against COVID-19. The COVID-19 mRNA vaccines do not contain replicable vaccine viruses, which means that vaccinated persons cannot transmit vaccine viruses to other persons.

The mRNA contained in the vaccines is not incorporated into the human genome after vaccination, but is "read" after entering the 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 generated against the spike protein of the virus. This produces a protective immune response.

The mRNA contained in the vaccine is degraded in the body after a few days. At that point, virus protein (spike protein) is no longer produced.

How is the vaccine administered?

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 6 weeks between the 1st and 2nd vaccination. At the present time, for the 2nd vaccination, the same vaccine from the same manufacturer must be used as for the 1st 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 COVID-19 Vaccine Moderna® from Moderna).

How effective is the vaccine?

The available COVID-19 mRNA vaccines are comparable in terms of efficacy as well as potential vaccine reactions and complications.

According to the current level of knowledge, the COVID-19 mRNA vaccines provide a high efficacy rate of approximately 95%. The current study data show that the probability of becoming infected with COVID-19 was approximately 95% lower for those vaccinated against COVID-19 than for those who were not vaccinated. Efficacy in preventing severe COVID-19 disease (that is, hospitalisation, for example) was approximately 85%. This means that if a person vaccinated with a COVID-19 vaccine comes into contact with the pathogen, there is a high probability that they will not become ill. How long this vaccine protection lasts is not yet known.

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?

COVID-19-mRNA vaccines are approved for persons 16 years and older (Comirnaty®) or 18 years and older (COVID-19 Vaccine Moderna®). 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 (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.

Who should not be vaccinated?

Children and adolescents up to and including 15 years of age, for whom no vaccine is currently approved, should not be vaccinated.

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 1st vaccination should not receive the 2nd vaccination.

Persons without immunodeficiency, for whom an infection with the novel coronavirus has been reliably proven, can be vaccinated at the earliest of 6 months after recovery or after diagnosis and should then receive only one vaccination dose. It is currently not possible to say whether or not a 2nd vaccination will be necessary in such persons at a later date. According to the recommendation of STIKO, individuals for whom an infection with the novel coronavirus was reliably proven after the 1st vaccination can receive the 2nd vaccination at the earliest of 6 months after the infection. 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 mRNA vaccines during pregnancy. 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 following a thorough explanation.
STIKO considers it highly unlikely that vaccination of the mother during breastfeeding poses a risk to the infant.

Prior to vaccination, please inform the doctor if you have a coagulation disorder or are taking anticoagulant medication. You can be vaccinated with simple precautions. Persons with an immune deficiency can receive the vaccine. 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 practitioner administering the vaccine. He/she can then potentially observe 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.

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

Following vaccination with the mRNA vaccines, local and general reactions can occur as an expression of the interaction of the body with the vaccine. These reactions occur most often within 2 days after the vaccination and rarely persist longer than 1 to 2 days.

Comirnaty®: The most frequently reported reactions to the vaccine in the approval studies were pain at the injection site (more than 80%), fatigue (more than 60%), headaches (more than 50%), muscle

pain and shivering (more than 30%), joint pain (more than 20%), as well as fever and swelling of the injection site (more than 10%). Nausea and redness around the injection site occurred frequently (between 1% and 10%). Swelling of the lymph nodes, insomnia, pain in the arm or leg, discomfort, and itchiness around the injection site occurred occasionally (between 0.1 and 1%).

COVID-19 Vaccine Moderna®: The most frequently reported reactions to the vaccine in the approval studies were pain at the injection site (more than 90%), tiredness (70%), headache and muscle pain (more than 60%), joint pain and shivering (more than 40%), nausea or vomiting (more than 20%), swelling or pain sensitivity of the lymph nodes in the armpits, fever, swelling and redness at the injection site (respectively more than 10%). A common rash as well as a rash, redness or hives at the injection site were frequently (between 1% and 10%) reported. Occasionally (between 0.1% and 1%), itchiness developed at the injection site.

In older persons, most reactions are observed somewhat less often than in younger persons. The vaccination reactions are mostly pronounced to be mild or moderate and occur somewhat more frequently after the second vaccination.

Are complications possible due to the vaccine?

Vaccine-related complications are consequences of the vaccine exceeding the normal extent of a vaccine reaction, which significantly impact the health of the vaccinated person.

During the extensive clinical trials prior to approval, 4 cases (between 0.1% to 0.01%) of acute facial paralysis were observed after administering Comirnaty®, which subsided after a few weeks in all the cases. Such facial paralyses may be causally related to the vaccination.
During the extensive clinical trials prior to approval, 3 cases of acute facial paralysis were observed after administering COVID-19 Vaccine Moderna®; 1 case occurred in the control group of unvaccinated persons. In all cases, the facial paralysis subsided after a few weeks. Further studies are being conducted to determine if there is a causal connection between such facial paralyses and the vaccine. In very rare cases, hypersensitivity reactions (2 cases of facial swelling) were observed.

Since introducing the vaccine, anaphylactic reactions (immediate allergic reactions) have been reported in very rare cases. These occurred shortly after administering the vaccine and required medical treatment.
So far, several million doses of the mRNA-COVID-19 vaccines have been administered in Germany. The adverse reactions previously reported to the Paul Ehrlich Institute after vaccination with mRNA vaccines were mainly temporary local and general reactions, which were also reported in the clinical trials prior to approval.

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:

_____	_____
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. 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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scope of its purpose. Any editing or modification is prohibited.

in Kooperation mit

Medical history for preventive vaccination against COVID-19 (Coronavirus Disease 2019) – with mRNA vaccine – (Comirnaty® from BioNTech/Pfizer and COVID-19 Vaccine Moderna® from Moderna)

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

0 Yes 0 No

2. Have you[1] already received 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 1st 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 from 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. Have you[1] ever experienced 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 potentially be answered by the legal representative.

Declaration of Consent for preventive vaccination against COVID-19 (Coronavirus Disease 2019)

–with mRNA vaccine – (Comirnaty® from BioNTech/Pfizer and COVID-19 Vaccine Moderna® from Moderna)

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 mRNA 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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