

## INFORMATION SHEET

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

#### – with mRNA vaccines –

As of 11 January 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 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 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), the vaccine offers the best possible illness protection.

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

The mRNA COVID-19 vaccines discussed here (BioNTech/Pfizer's Comirnaty® and Moderna's COVID-19 Vaccine Moderna®) are genetically engineered vaccines that are based 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 vaccine against COVID-19. This spike protein is harmless in its own right. The vaccine is thus not infectious.

The mRNA contained in the vaccine is not integrated into human DNA, but rather decomposes in the body after a few days. Virus protein is then no longer produced.

The spike proteins generated by the body of the vaccinated person after receiving the vaccine (primarily in muscle cells at the vaccination site and in certain immune cells) are recognised as foreign proteins by the immune system, wherefore specific immune cells are activated and antibodies against the spike protein of the virus as well as immune cells are generated. This produces a protective immune response.

**How is the vaccine administered?**

The vaccine is injected into the upper arm muscle. For adequate immunisation, the vaccine must be administered twice. There should be at least 3 weeks (Comirnaty®) or 4 weeks (COVID-19 Vaccine Moderna®) between the 1st and 2nd vaccination. However, for both vaccines, there should be no more than 6 weeks between the two vaccinations. For the 2nd vaccination, the same vaccine from the same manufacturer must be used as for the 1st vaccination.

**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.

The clinical trials seem to suggest vaccine protection beginning from the period of 7 days (Comirnaty®) or 14 days (COVID-19 Vaccine Moderna®) after the 2nd vaccination. According to the current level of knowledge, the COVID-19 mRNA vaccines provide a high efficacy rate of up to 95% (Comirnaty®) and 94% (COVID-19 Vaccine Moderna®). The study data show that the probability of becoming infected with COVID-19 was 95% or 94% lower for those vaccinated against COVID-19 than for those who were not vaccinated. 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. 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 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?**

COVID-19-mRNA vaccines are approved for persons 16 years and older (Comirnaty®) or 18 years and older (COVID-19 Vaccine Moderna®). 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. This is the assessment of STIKO (Standing Committee on Immunisation at the Robert Koch Institute) in light of the prioritisation criteria developed together with the German Ethics Council and the Leopoldina.

**Who should not be vaccinated?**

Children and adolescents under 16 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, in whom a past infection with the novel coronavirus was proven, are not compelled to be vaccinated for the time being. 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 mRNA vaccines during pregnancy and breastfeeding.

STIKO does not currently recommend general vaccination during pregnancy. 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.

### **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 (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 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 previous observation period of several months were pain at the injection site (more than 80%), fatigue (more than 60%), headaches 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 during the previous mostly two-month observation period were pain at the injection site (more than 90%), fatigue (70%), headache and muscle pain (more than 60%), joint pain and shivering (more than 40%), nausea or vomiting (more than 20%), swelling 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 and 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, hypersensitivity reactions have been reported in very rare cases. These occurred shortly after administering the vaccine 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, 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 the legal representative)

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 mRNA 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 1st 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 potentially be answered by the legal representative.

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

Signature of the practitioner

legal care provider or guardian)

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