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INFORMATION SHEET

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

– with mRNA vaccines –

As of: 22 December 2020 (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), has been circulating around the world, which is the pathogen of COVID-19 (Corona Virus Disease 2019).

Frequent symptoms of COVID-19 include a dry cough, fever (above 38 °C), 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 vaccine (Comirnaty®) discussed here is a genetically engineered vaccine that is based on a 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 after receiving the vaccine (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 virus as well as immune cells are generated. This produces a protective immune response.

For adequate immunisation, the vaccine must be administered twice at an interval of 3 weeks. In doing so, the vaccine is injected in the upper arm muscle.

How effective is the vaccine?

Sufficient immunisation starts 7 days after the 2nd vaccination. According to the current level of knowledge, approx. 95 out of 100 vaccinated persons are protected from becoming ill. It is not yet known how long this protection lasts. Because protection does not set in immediately after vaccination and is not present in all vaccinated persons, despite being vaccinated it is also necessary to protect yourself and your environment by following the safety rules (social distancing, hygiene, wearing a facemask and ventilation of rooms).

Who benefits in particular from the vaccine?

The COVID-19-mRNA vaccine is approved for persons 16 years and older and the mid-term goal is to be able to provide a COVID-19 vaccine to all persons over 16 years of age. 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 position paper prepared together with the German Ethics Council and the Leopoldina.

Who should not be vaccinated?

Children and youth under 16 years of age, for whom the vaccine is not currently approved, should not be vaccinated. As there is not yet sufficient experience, the vaccine is currently only recommended during pregnancy or if nursing after individual consideration of the risks and benefits.

Those suffering with an acute illness accompanied by a fever over 38.5°C 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.

Persons, in whom a past infection with the novel coronavirus was proven, are not compelled to be vaccinated for the time being, although nothing speaks against being vaccinated.

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 vaccine (Comirnaty®), 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.

The most frequently reported reactions to the vaccine in the previous two-month observation period were pain at the injection site (more than 80%), fatigue (more than 60%), headaches and chills (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%).

In older person, 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% and 0.01%) of acute facial paralysis were observed after administering the mRNA vaccine referred to in this information sheet. Further studies are being conducted to determine if there is a causal connection between them and the vaccine. Other serious complications were not observed during the clinical trials. Since introducing the vaccine, hypersensitive reactions have been report in very rare cases. These occurred shortly after administering the vaccine and required medical treatment. As is the case with all vaccines, other 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

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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 administering the vaccine	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.

You can find additional information about COVID-19 and about the COVID-19 vaccine at
https://www.zusammengegencorona.de/informieren/informationen-zum-impfen/

https://www.bzga.de/

www.rki.de/covid-19-impfen

https://www.pei.de/DE/newsroom/dossier/coronavirus/coronavirus-inhalt.html

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Medical history for the COVID-19 vaccine – with mRNA vaccine

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

0 Yes 0 No

2. Do you* suffer from chronic diseases or immune weakness (e.g. due to chemotherapy or other medications)?

0 Yes 0 No

If yes, which_____

3. Do you* suffer from a coagulation disorder or do you take blood-thinning medication?

0 Yes 0 No

4. Do you* have any known allergies?

0 Yes 0 No

If yes, which _____

5. Did you* have any allergic symptoms, high fever, fainting spells or other uncommon reactions following a previous vaccine?

0 Yes 0 No

If yes, which _____

6. For women of a childbearing age: Are you currently pregnant or nursing*?

0 Yes 0 No

7. Have you* been vaccinated in the last 14 days?

0 Yes 0 No

* This will potentially be answered by the legal representative

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Declaration of Consent for the COVID-19 vaccine – with mRNA vaccine

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

_____

Date of birth: _____

Address: _____

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 the legal representative
(custodian or guardian)

Signature of the practitioner