

Informed Consent of the Patient to Administration of the COMIRNATY Vaccine

Patient

Name and surname

Place of residence

Date of Birth

Health Insurance

Company

Legal Guardian

Witness

Name and surname

Place of residence

Date of Birth

Relationship to Patient

I. Information about the Proposed Procedure

Vaccination against COVID-19 with the COMIRNATY vaccine (hereinafter referred to as the “vaccine”). The vaccine will be injected into your shoulder muscle. After administration of the vaccine, careful monitoring of your health is usually recommended for a period of thirty minutes at the vaccination site.

II. Expected Benefit of the Procedure

The vaccine is intended to prevent you from contracting the COVID-19 disease caused by the SARS-CoV-2 virus.

For full effect, you need to be vaccinated with two doses. The second dose will be administered to you in the same way at the earliest 21 days after the first dose, in accordance with the valid measure of the Ministry of Health of the Czech Republic. The vaccinating physician will inform you about the date of the second vaccination. It is very important that you also receive the second dose, otherwise the vaccine may not protect you at all or does not protect you enough against COVID-19.

After administration, the vaccine triggers a natural production of antibodies and stimulates the immune cells to protect you against COVID-19.

Protection against COVID-19 may not be sufficient until the seventh day after the second dose of the vaccine. Until then, it is necessary to behave according to the recommended hygienic-epidemiological instructions to protect one’s own health and the health of others.

III. Risks of the Procedure

Some people may have an allergic reaction after receiving the vaccine, which may include an itchy rash, difficulty breathing, swelling of the face or tongue. If you experience such an allergic reaction, contact your general practitioner immediately.

Without the timely help of a doctor, personal injury may occur and in exceptional cases, the patient's life may be endangered.

Consult your general practitioner if you intend to be vaccinated against COVID-19 if:

- you have had a severe allergic reaction to another vaccine, medicine or food,
- you have had problems after receiving the first dose of the COVID-19 vaccine, such as an allergic reaction or difficulty breathing,
- you now suffer from a severe disease accompanied by high fever; however, mild fever or mild upper respiratory tract infection such as cold or recovery from a previous COVID-19 infection are not a reason to delay the vaccination,
- you have a weakened immune system, e.g. due to HIV infection or are taking medicines that negatively affect the immune system,
- you have haemorrhage problems, get bruises easily or are taking medicines that reduce blood's clotting ability.

If you are pregnant, breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician about the vaccination. Vaccination is not recommended to pregnant or breast-feeding women.

If, after consulting your physician, you have doubts about the suitability of vaccination due to your specific situation (e.g. rare disease, rare combination of disease or disability, etc.), do not hesitate to consult your specialist. Tell your vaccinating physician about your complications before vaccinating.

The vaccine may cause adverse effects. If they do occur, they are usually mild and wear off in a few days.

More than one in ten people who are vaccinated may experience pain or swelling at the injection site, tiredness, headache, muscle or joint pain, chills or fever.

Less than one in ten people who are vaccinated may experience swelling or redness at the injection site or feeling sick (vomiting).

Less than one in a hundred vaccinees may experience lymph node enlargement or weariness.

If you get any side effects, consult your general practitioner.

As with other vaccines, this vaccine may not fully protect the vaccinee against the disease.

If you have any questions about the vaccine or vaccination process, ask your vaccinating physician.

IV. Procedure Alternatives

There are currently no known procedure alternatives.

V. Treatment Regimen, Preventive Measures, Inspection Procedures

Avoid significant physical exertion two days after vaccination.

VI. Answers to Additional Questions of the Patient (or indicate that the Patient did not have any additional questions)

Patient's/Legal Guardian's Consent

I, the undersigned, hereby declare that the physician comprehensibly informed me about any of the above facts, the planned procedure, including possible complications. The physician has communicated and explained the facts and instructions to me, I have understood them and I had an opportunity to ask additional questions that have been answered. Based on the information provided and after my own consideration, I agree with the proposed procedure.

.....
Date

.....
Patient's (Legal Guardian's) signature

.....
Witness's signature

The Patient's reason for not signing the consent:

Physician's Statement

I declare that I have comprehensibly informed the above Patient (Legal Guardian) about all the above facts and proposed procedure, including possible complications that may occur.

.....
Date, time

.....
Physician's name and surname

.....
Physician's
signature