

Informed Consent of the Legal Representative of a Minor Patient to Administration of the COMIRNATY Vaccine

Data of a Minor Patient

Name and surname

Place of residence

Date of Birth

Health Insurance

Company

Data of a Legal Representative

Name and surname

Place of residence

Date of Birth

Phone Number

Relationship to Patient

Witness

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 child’s shoulder muscle. After administration of the vaccine, careful monitoring of their 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 your child from contracting the COVID-19 disease caused by the SARS-CoV-2 virus.

For full effect, your child needs to be vaccinated with two doses. The second dose will be administered to your child 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 your child also receives the second dose, otherwise the vaccine may not protect your child at all or does not protect your child enough against COVID-19.

After administration, the vaccine triggers a natural production of antibodies and stimulates the immune cells to protect your child 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 your child’s 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 your child experiences such an allergic reaction, contact your child's 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 child's general practitioner if you intend to vaccinate your child against COVID-19 if:

- your child has had a severe allergic reaction to another vaccine, medicine or food,
- your child has had problems after receiving the first dose of the COVID-19 vaccine, such as an allergic reaction or difficulty breathing,
- your child now suffers 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,
- your child has a weakened immune system, e.g. due to HIV infection or your child is taking medicines that negatively affect their immune system,
- your child has haemorrhage problems, gets bruises easily or is taking medicines that reduce their blood's clotting ability.

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

If, after consulting your child's physician, you have doubts about the suitability of vaccination due to your child's specific situation (e.g. rare disease, rare combination of disease or disability, etc.), do not hesitate to consult their specialist. Tell your child's vaccinating physician about their 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 your child gets any side effects, consult their 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 child's 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 Legal Representative of a Minor Patient, or a Minor Patient (or indicate that the Legal Representative of a Minor Patient, or a Minor Patient did not have any additional questions)

Legal Representative'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

.....
Legal Representative's signature

.....
Witness's signature

The Legal Representative's reason for not signing the consent:

Physician's Statement

I declare that I have comprehensibly informed the above Legal Representative of a Minor Patient (and with regard to the intellectual and volitional maturity of a Minor Patient also a Minor Patient) about all the above facts and proposed procedure, including possible complications that may occur.

.....
Date, time

.....
Physician's name and surname

.....
Physician's
signature