

## Informed consent of the patient to administration of the second booster dose 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 on the proposed procedure

You have already received the basic vaccination against COVID-19 (the “Vaccine”) and have been given the first booster dose.

The basic vaccination series in conjunction with a booster dose of the Vaccine continues to provide certain protection against the severe course of COVID-19 disease caused by the omicron variant, but the effectiveness of vaccination against infections and symptomatic diseases is lower and declines more rapidly over time. The elderly and people with immune deficiencies or chronic diseases (typical of other vaccinations as well) are at a greater risk of a decline in protection than others.

**For the above reasons, we suggest you receive the second booster dose of the Vaccine.** A booster dose of the Vaccine may be given no earlier than 4 months after the first booster dose in persons who have reached 18 years of age.

The booster dose of vaccine is to be injected into a shoulder muscle. Following its administration, close monitoring of your health condition is recommended, usually for 30 minutes, at the vaccination site.

### II. Expected benefit(s) of the procedure

After the booster dose has been administered, the vaccine will induce natural antibody production and stimulate immune cells to protect you against COVID-19 disease more intensely and quickly than previous doses of the vaccine.

The administration of a booster dose of the vaccine will reduce the likelihood of being infected by COVID-19 as well as the risk of its severe course significantly.

Even after the booster dose of the vaccine has been administered, it is important to follow recommended hygiene and epidemiological practices to protect your 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 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,
- you had problems after receiving the COVID-19 Vaccine, such as myocarditis or pericarditis.

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.

Myocarditis and pericarditis are rare after vaccination with mRNA vaccines against COVID-19. These cases are mild in the vast majority of cases and are more common in younger men and after second doses of the mRNA vaccine.

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**

#### **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