

## **ATTACHMENT TO THE ANTI-COVID-19 VACCINATION CONSENT FORM GENERAL INFORMATION**

### **Moderna COVID-19 Vaccine**

#### **What is the Moderna COVID-19 vaccine and what is it for?**

The Moderna COVID-19 vaccine is used to prevent COVID-19, the disease caused by the SARS-CoV-2 virus. The Moderna COVID-19 vaccine is administered to adults aged 18 and over. The vaccine induces the immune system (the body's natural defenses) to produce antibodies and blood cells against the virus, thereby providing protection against COVID-19. As no component of the Moderna COVID-19 vaccine contains the virus to induce immunity, it cannot transmit COVID-19.

#### **What do I need to know before receiving the Moderna COVID-19 vaccine?**

You must **not** receive the Moderna COVID-19 vaccine if you are allergic to the active ingredient or any other ingredient of this drug (see list below).

#### **Warnings and Precautions**

Inform your doctor or the health care worker at the vaccination center before receiving the vaccine if:

- you have ever had a severe allergic reaction or respiratory problems after any vaccine in the past or after having received the Moderna COVID-19 vaccine in the past;
- you have ever fainted after any sort of injection;
- you currently have a disease or a severe infection with high fever. However, if you have a low-grade fever or an infection of your upper airways, like a cold, you can receive the vaccine;
- you have a bleeding disorder, you bruise easily, or you are taking a blood thinner (to prevent the formation of blood clots)
- your immune system is weak due to a disease, like HIV infection, or you are taking any drugs that weaken your immune system, like corticosteroids.

#### **Other medications and the Moderna COVID-19 vaccine**

Inform your doctor or the health care worker at the vaccination center before receiving the vaccine if you are taking or have recently taken any other type of drug or if you have recently received any other vaccine.

#### **Pregnancy and breastfeeding**

If you are pregnant, think you are pregnant, or planning to become pregnant, or if you are breastfeeding, ask your doctor for advice before receiving this vaccine.

There is limited information on the use of the Moderna COVID-19 vaccine in pregnant women. Studies on animals have shown that the Moderna COVID-19 vaccine does not have any direct or indirect effect on pregnancy, on embryonal or fetal development, on childbirth or on the baby's development after birth. Receiving the Moderna COVID-19 vaccine while pregnant can be taken into consideration only when the potential benefits outweigh the potential risks to the mother and to the fetus.

#### **Duration of protection and limitations of the effectiveness of the vaccine**

The duration of the protection the vaccine provides is unknown; clinical studies are underway to establish this.

As with all vaccines, vaccination with the Moderna COVID-19 vaccine may not protect all vaccinated individuals. Individuals may not be completely protected until 14 days after the second dose of the vaccine. It is therefore essential to scrupulously continue following all public health recommendations (mask wearing, physical distancing, frequent hand washing).

## How is the Moderna COVID-19 vaccine administered?

The Moderna COVID-19 vaccine is administered as an intramuscular injection in your upper arm. A second dose is necessary, and it is recommended that this second dose of the same vaccine be administered 4 weeks (and in any case not after more than 42 days) after the first dose to complete the vaccination cycle. It is very important that the second dose be administered to obtain the optimum response from your immune system. Should you forget to return for your second dose on the scheduled date, contact your doctor or the vaccination center where you received the first dose.

## Possible side effects

Like all vaccines, the Moderna COVID-19 vaccine may cause side effects, although not everyone will have them.

*Very common* (more than 1 person out of 10):

- swelling in the armpits
- headache
- nausea, vomiting
- muscle pain, joint pain and stiffness
- pain or swelling at the injection site
- extreme fatigue
- chills, fever

*Common* (up to 1 person out of 10):

- rash
- redness or hives at the injection site

*Uncommon* (up to 1 person out of 100):

- itching at the injection site

*Rare* (up to 1 person out of 1,000):

- temporary unilateral flaccid facial paralysis (Bell's palsy)
- swelling of the face (may appear in those patients who underwent cosmetic facial injections in the past)

*Unknown* (the frequency cannot be established based on the data available): severe allergic reaction; hypersensitivity.

If any side effect occurs, even if not listed above, contact your doctor or the vaccination center.

You can also report side effects directly through the national reporting system:

<https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>.

## What does the Moderna COVID-19 Vaccine contain?

The active ingredient is mRNA anti-COVID-19. The other ingredients are: Lipid SM-102, cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG), tromethamol, tromethamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injection preparations.