

ATTACHMENT TO THE COVID-19 VACCINATION CONSENT FORM:**INFORMATION LEAFLET 1****Moderna COVID-19 Vaccine****What the Moderna COVID-19 Vaccine is and what it is used for**

The Moderna COVID-19 Vaccine is a vaccine used to prevent COVID-19 disease caused by SARS-CoV-2 virus. The Moderna COVID-19 Vaccine is given to adults from 18 years. The vaccine triggers the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, to protect against COVID-19 disease. The Moderna COVID-19 Vaccine does not contain the virus to trigger immunity and therefore cannot transmit COVID-19.

What you need to know before you receive the Moderna COVID-19 Vaccine

The Moderna COVID-19 Vaccine should not be given if you are allergic to the active substance or any of the other ingredients of this medicine (listed below).

Warnings and precautions

Talk to the doctor or health care professional at the vaccination centre before you are given the vaccine if you have:

- ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given the Moderna COVID-19 Vaccine in the past;
- fainted after an injection;
- a severe illness or infection with high fever. However, if you have a mild fever or an upper airway infection (like a cold), you can still receive the vaccination;
- a bleeding problem, bruise easily or use a medicine to inhibit blood clotting;
- a weakened immune system, due to a disease such as HIV infection, or are on a medicine that affects your immune system, such as corticosteroids.

Other medicines and the Moderna COVID-19 Vaccine

Tell the doctor or health care professional at the vaccination centre if you are using, have recently used, or might use any other medicines, or have recently received any other vaccine.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, or if you are breast-feeding, ask the doctor for advice before you receive this vaccine.

Information relating to the use of the Moderna COVID-19 Vaccine in pregnant women is limited. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. Administration of the Moderna COVID-19 Vaccine in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Duration of protection and limitations of vaccine effectiveness

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials. As with any vaccine, vaccination with the Moderna COVID-19 Vaccine may not protect all vaccine recipients. Individuals may not be fully protected until 14 days after their second dose of vaccine. It is therefore essential to continue to strictly adhere to public health advice (mask, social distancing and frequent hand washing).

How the Moderna COVID-19 Vaccine is given

The Moderna COVID-19 Vaccine is injected into a muscle in the upper arm (intramuscular injection). A booster will be given and it is recommended that the second dose of the same vaccine is given 4 weeks (and in any case no more than 42 days) after the first dose to complete the vaccination cycle.

It is very important that you get the second dose to achieve an optimal immune response. If you miss your scheduled appointment for the second dose, contact your doctor or the vaccination centre where you received the first dose.

Possible side effects

Like all vaccines, the Moderna COVID-19 Vaccine can cause side effects, although not everybody gets them. *Very common side effects* (may affect more than 1 in 10 people):

- swelling in the armpit
- headache
- nausea, vomiting
- muscle ache, joint aches, and stiffness
- pain and swelling at injection site
- feeling very tired
- chills, fever

Common side effects (may affect up to 1 in 10 people):

- rash
- redness or hives at injection site

Uncommon side effects (may affect up to 1 in 100 people):

- injection site itching

Rare side effects (may affect up to 1 in 1,000 people):

- temporary one sided facial drooping (Bell's palsy)
- swelling of the face (swelling of the face may occur in patients who have had facial cosmetic injections.)

Not known (cannot be estimated from the available data): severe allergic reaction; hypersensitivity.

If you get any side effects, even if not listed above, talk to your doctor or contact the vaccination centre.

You can also report any side effects directly through the national reporting system (<https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>).

What the Moderna COVID-19 Vaccine contains

The active substance is a COVID-19 mRNA Vaccine.

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); trometamol; trometamol hydrochloride; acetic acid; sodium acetate trihydrate; sucrose; water for injections.

