

ATTACHMENT TO THE ANTI-COVID-19 VACCINATION CONSENT FORM

GENERAL INFORMATION

COMIRNATY (BioNTech/Pfizer)

What is Comirnaty and what is it for?

Comirnaty is used to prevent COVID-19, the disease caused by the SARS-CoV-2 virus. Comirnaty is administered to adults and adolescents aged 16 and over. The vaccine induces the immune system (the body's natural defenses) to produce antibodies and active blood cells against the virus, thereby providing protection against COVID-19. As Comirnaty does not contain the virus to induce immunity, it cannot transmit COVID-19.

What do I need to know before receiving Comirnaty?

You must not receive Comirnaty if you are allergic to the active ingredient or any other component of this vaccine (see list below).

Warnings and Precautions

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

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

Other medications and Comirnaty

Inform your doctor or the health care workers at the vaccination center if you are using, have recently used, or may use any other medication, or if you have recently received another 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 before receiving this vaccine.

There is limited information on the use of Comirnaty in pregnant women. Studies on animals have shown that Comirnaty does not have any direct or indirect harmful effect on pregnancy, on embryonal or fetal development, on childbirth or on the baby's development after birth. Receiving Comirnaty 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 provided by the vaccine is unknown; clinical studies are underway to establish this. As with all vaccines, Comirnaty may not protect everyone who receives it. Subjects may not be completely protected until 7 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 Comirnaty administered?

Comirnaty is administered after dilution as an intramuscular injection in the upper arm. A second dose is foreseen, and it is recommended that the second dose be administered 3 weeks (and in any case not after 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, Comirnaty may cause side effects, although not everyone manifests them.

Very common side effects (in more than 1 person out of 10):

- pain and swelling at the injection site
- fatigue
- headache
- muscle pain
- chills
- joint pain
- diarrhea
- fever

Common side effects (up to 1 person out of 10):

- redness at the injection site
- nausea
- vomiting

Uncommon side effects (up to 1 person out of 100):

- swelling of lymph nodes
- malaise
- limb pain
- insomnia
- itching at the injection site
- allergic reaction like rash or itching

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

- temporary asymmetry of one side of the face
- allergic reaction like hives or swelling of the face

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

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 Comirnaty contain?

The active ingredient of the vaccine is mRNA anti-Covid-19. The other ingredients are ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315); 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159); 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC); cholesterol; potassium chloride; potassium dihydrogen phosphate; sodium chloride; disodium phosphate dehydrate; sucrose; water for injection preparations.