

Version 02. of 20/04/2021

**ATTACHMENT TO THE COVID-19 VACCINATION CONSENT FORM:  
INFORMATION LEAFLET****COMIRNATY (BioNTech/Pfizer)****What Comirnaty is and what it is used for**

Comirnaty is a vaccine used to prevent COVID-19 disease caused by SARS-CoV-2 virus. Comirnaty is given to adults and adolescents from 16 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. Comirnaty does not contain the virus to trigger immunity and therefore cannot transmit COVID-19.

**What you need to know before you receive Comirnaty**

Comirnaty 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 Comirnaty 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 Comirnaty**

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 Comirnaty 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 Comirnaty 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 Comirnaty may not protect all vaccine recipients. Individuals may not be fully protected until 7 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 Comirnaty is given

Comirnaty is given after dilution into a muscle in the upper arm (intramuscular injection). A booster will be given and it is recommended that the second dose is given 3 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, Comirnaty can cause side effects, although not everybody gets them.

*Very common side effects* (may affect more than 1 in 10 people):

- at injection site: pain, swelling
- tiredness
- headache
- muscle pain
- chills
- joint pain
- diarrhoea
- fever

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

- redness at injection site
- nausea
- vomiting

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

- enlarged lymph nodes
- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching

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

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

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

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 Comirnaty contains

The active substance is a COVID-19 mRNA Vaccine.

The other ingredients are: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315); 2-[[poly(ethylene 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 dihydrate; sucrose; water for injections.