ATTACHMENT 1 TO THE COVID-19 VACCINATION CONSENT FORM

INFORMATION LEAFLET 1

COMIRNATY (BioNTech/Pfizer)

What Comirnaty is and what it is used for

Comirnaty is a vaccine used to prevent COVID-19, a disease caused by the SARS-CoV-2 virus. Comirnaty is administered to adults and adolescents aged 12 years and older. The vaccine triggers the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, thus providing protection against COVID-19. Comirnaty does not contain the virus to trigger immunity and therefore cannot transmit COVID-19.

What you need to know before you are given Comirnaty

Comirnaty should not be administered 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 the healthcare 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;
- have ever fainted following an injection;
- have an illness or a severe 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;
- have a bleeding problem, bruise easily or use a medicine to inhibit blood clotting;
- have 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.

Very rare cases of myocarditis (inflammation of the heart) and pericarditis (inflammation of the outer lining of the heart) have been reported following vaccination with Comirnaty, occurring mainly within two weeks after vaccination, more often after the second dose and in younger men. After vaccination, it is necessary to watch out for signs of myocarditis and pericarditis, such as shortness of breath, palpitations and chest pain, and seek immediate medical attention if such symptoms occur.

Other medicines and Comirnaty

Tell the doctor or the healthcare professional at the vaccination centre if you are taking, have recently taken, or might take any other medicines, or if you 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, seek medical 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. The administration of Comirnaty during pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and the 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 the second dose of the vaccine.

It is therefore essential to continue to strictly adhere to public health guidelines (face masks, social distancing and frequent hand washing).

How Comirnaty is administered

Comirnaty is administered after dilution through an intramuscular injection into the upper arm. A booster shot will be scheduled, and it is recommended that the second dose of the same vaccine 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 family doctor or the vaccination centre where you received the first dose.

For severely immunocompromised people, an additional dose should be scheduled at least 28 days after the second dose, in order to ensure a good immune response. Currently, the use of additional doses is still under evaluation by the EMA (European Medicines Agency), but the Italian Medicines Agency (AIFA) has allowed it as a precautionary measure, by including the drug in the lists drawn up according to law no. 648/96[1].

Comirnaty can be used to complete a mixed vaccination schedule in subjects below 60 years of age who have already received a first dose of Vaxzevria, 8-12 weeks after the administration of this vaccine. This use is not included in the indications of the vaccine, but, following the Ministry's circular letter ref. no. 0026246-11/06/2021-DGPRE, the Italian Medicines Agency (AIFA) has allowed its use, through the inclusion of the drug in the lists drawn up in accordance with Law no. 648/96[1], for individuals under the age of 60 who previously received Vaxzevria. This authorisation was made possible by the recent publication of clinical data showing a good antibody response and manageable side effects following a mixed vaccination schedule.

Possible side effects

Like all vaccines, Comirnaty may cause side effects, although not everybody shows them.

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

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

Some of these side effects were slightly more common in adolescents aged 12 to 15 years than in adults.

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
- pain in the limbs
- insomnia
- itching at the injection site
- allergic reactions such as rash or itching

[1] Law no. 648/96 allows doctors to use medicaments that have proven to be effective and safe in the treatment of a specific disease, but which are not authorized for that specific therapy, at the expense of the National Health Service.

Rare side effects (may affect up to 1 in 1000 people):

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

Not known (frequency cannot be estimated from the available data):

- severe allergic reaction
- inflammation of the heart (myocarditis) or inflammation of the outer lining of the heart (pericarditis) which can cause shortness of breath, palpitations or chest pain

If you experience any possible side effects, even if not listed above, talk to your family 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-[(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 dihydrate; sucrose; water for injections.