# Vaccination with Pfizer (Comirnaty) COVID-19 mRNA BNT162b2 vaccine
# AIFA FAQs

## VACCINE FEATURES

**(Comirnaty) COVID-19 mRNA BNT162b2 vaccine**
COVID-19 mRNA vaccine.

**1.What is it and what is it used for?**
(Comirnaty) COVID-19 mRNA BNT162b2 vaccine is a vaccine indicated for preventing coronavirus disease 2019 (COVID-19) in people aged 16 years and older. It contains a molecule called messenger RNA (mRNA) with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID-19. The vaccine does not contain the virus itself and cannot cause the disease.

**2. How is it used?**
(Comirnaty) COVID-19 mRNA BNT162b2 vaccine is given as two injections, usually into the deltoid muscle of the upper arm, at least 21 days apart.

**3. How does it work?**
SARS-CoV-2 viruses infect the body by using a protein on their surface, called spike protein, that allows the viruses to penetrate into the body's cells and reproduce themselves.
Vaccines currently being studied have been developed to induce a response that blocks the spike protein, thus preventing cells infection.
(Comirnaty) COVID-19 mRNA BNT162b2 vaccine contains messenger RNA (mRNA) molecules with instructions for the cells of the vaccinated person's body to produce the spike protein. The vaccine's mRNA molecules are covered in small lipid (fat) particles that help deliver the mRNA into the cells. Once injected, the mRNA is absorbed by the cell cytoplasm and starts producing the spike protein.
The proteins so produced stimulate the immune system to produce specific antibodies. When a vaccinated person comes into contact with the virus, the antibodies block the spike proteins of the virus and prevent them from entering into the body's cells.
Additionally, the vaccination activates T cells that prepare the immune system to respond to further contacts to SARS-CoV-2.
Therefore, the vaccine does not introduce the virus itself into the body of the person receiving the vaccine. It only delivers the genetic information that cells need to produce copies of the spike protein. If, later on, the person comes into contact again with SARS-CoV-2 virus, their immune system will recognise it and be ready to defend the body against it.
The mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination.

**4. What does it contain?**

(Comirnaty) COVID-19 mRNA BNT162b2 vaccine contains messenger RNA (mRNA) that is unable to spread in the host cells. It induces the production of SARS-CoV-2 virus antigens. The S antigens of the virus stimulate the immune system response of the body of the vaccinated person, which produces neutralising antibodies.

The mRNA is covered in ALC-0315 ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate) and ALC-0159 (2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide) liposomes. ALC-0315 and ALC-0159 are synthetic lipids that help form the vesicles that carry the vaccine. The vaccine also contains the following excipients:

- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- disodium phosphate dihydrate
- potassium dihydrogen phosphate
- potassium chloride
- sodium chloride
- sucrose
- water for injections

**VACCINATION EFFICACY AND SAFETY**

**5. Has the clinical trial duration been shortened in order to obtain the product sooner?**

Studies on COVID-19 vaccines, including (Comirnaty) COVID-19 mRNA BNT162b2 vaccine, began in spring 2020. Therefore, they lasted a few months compared to usual times, but saw the participation of a very large number of people, ten times higher than usual vaccine development studies. Therefore, it was possible to carry out a sufficiently large study to demonstrate the vaccine's efficacy and safety.

None of the regular phases for the verification of the vaccine's efficacy and safety was skipped: the short timelines leading to the swift approval were possible thanks to the research already carried out for many years on RNA vaccines, to the great human and financial resources made available in a very short time and to the assessment, by the regulatory agencies, of the results obtained as they became available and not, as usually happens, when all studies were completed. These simple measures saved years on approval times.

**6. How were clinical trials conducted?**

A very large clinical trial showed that (Comirnaty) COVID-19 mRNA BNT162b2 vaccine was effective at preventing COVID-19 in people from 16 years of age.

The vaccine's safety and efficacy were assessed in trials across six countries (USA, Germany, Brazil, Argentina, South Africa and Turkey), involving more than 44,000 people.

Half received the vaccine and half were given placebo, a product identical to the vaccine but inactive. Efficacy was calculated in over 36,000 people aged 16 years and older (including people over 75 years of age) who had no sign of previous infection.

The study showed a 95% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (8 cases out of 18,198 got COVID-19 symptoms) compared with people who received placebo (162 cases out of 18,325 got COVID-19 symptoms).

**7. How effective is it?**

Trial findings showed that two injections of (Comirnaty) COVID-19 mRNA BNT162b2 vaccine given 21 days apart can prevent 95% of adults aged 16 years and older to develop COVID-19. Such findings were maintained across age groups, genders and ethnic groups.
The 95% reduction refers to the difference between the 162 cases in over 18,000 people who received placebo and the only 8 cases in over 18,000 people who received the vaccine.

**8. Is protection active right after the vaccination?**
No, effectiveness has been shown to be active one week after the second injection.

**9. How long does protection from the vaccine last?**
It is not currently known how long protection given by the vaccine lasts, since the observation period inevitably lasted few months. However, evidence from other coronavirus strains shows that protection should last at least 9-12 months.

**10. Can the vaccine cause COVID-19 or other genetic modifications?**
This vaccine does not use active viruses. It only carries a genetic component that delivers into the body the instructions to produce specific antibodies.
Whole or live viruses are not involved, so the vaccine cannot cause diseases. Like all mRNAs produced by cells, the vaccine's mRNA naturally degrades a few days after the vaccination.

**11. Can vaccinated people spread the virus to others?**
Clinical trials conducted so far have allowed to assess the efficacy of (Comirnaty) COVID-19 mRNA BNT162b2 vaccine on clinically manifest forms of COVID-19. More time is needed to obtain significant evidence that shows whether vaccinated people can become asymptomatically infected and then infect other people. Although vaccination is likely to protect against infection, vaccinated people and those with whom they come into contact should continue to take protective measures against COVID-19.

**12. Can people who receive the first dose of (Comirnaty) COVID-19 mRNA BNT162b2 vaccine complete the vaccination course with a second dose of a different COVID-19 vaccine, if available?**
There are no data available on the interchangeability among different COVID-19 vaccines to complete the vaccination course. People who have received one dose of COVID-19 mRNA BNT162b2 vaccine should receive a second dose of the same vaccine.

**13. What adverse reactions have been observed?**
The most frequent adverse reactions (affecting more than 1 in 10 people) observed (Comirnaty) COVID-19 mRNA BNT162b2 vaccine in the trial were usually mild or moderate and resolved within a few days after vaccination. These included pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills and fever.
Redness at the injection site and nausea occurred in less than 1 in 10 people. Itching at the injection site, pain in the limb, enlarged lymph nodes, difficulty sleeping and feeling unwell were uncommon adverse reactions (affecting less than 1 in 100 people). Weakness in muscles on one side of face (acute peripheral facial paralysis or palsy) occurred rarely in less than 1 in 1,000 people.

**14. What serious adverse reactions were observed during the trial?**

The most common serious adverse reaction occurring in the vaccine group compared with the placebo group was the enlargement of lymph nodes. However, this benign condition resolves naturally.
Generally, systemic reactions were more frequent and pronounced after the second dose.
Reports of adverse reactions, from the least serious to the most significant, including allergic reactions, are being collected in countries where mass administration of the vaccine has already started. All countries administering the vaccine to the whole population will collect and assess any adverse reaction reported to the relevant pharmacovigilance system in order to be able to define the risk profile associated with the vaccine as accurately as possible.

**15. Where can adverse reactions be reported?**
Like all adverse reactions to medicinal products, adverse reactions to the vaccine can be reported to general practitioners and to the local health authorities (ASL), in agreement with the pharmacovigilance system in place.
Additionally, adverse reactions can be reported via AIFA's website:
https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse.

**16. How is the absence of contraindications guaranteed?**
Before vaccination, healthcare professionals (HCP) will ask the person who is going to receive the vaccine a series of precise and simple questions, using a standardised card. Based on the answers given by the person, HCPs will consider whether vaccination should be carried out or postponed. In addition, HCPs shall verify whether there are contraindications or special precautions need to be taken, as reported in the vaccine data sheet.

**17. A new SARS-CoV-2 virus variant has been detected. Will the vaccine be effective also against it?**
RNA viruses, such as SARS-CoV-2, are subject to frequent mutations, most of which do not significantly alter the structure and components of the virus. Many variants of SARS-CoV-2 were reported in 2020, but so far these variants have not altered the natural behaviour of the virus.
The variant reported in the UK is the result of a series of surface protein mutations, and assessments are being carried out of the effects that these may have on the course of the epidemic. A negative effect on vaccination is unlikely.

**SPECIAL CONDITIONS**

**18. Can/Must people who have already had confirmed COVID-19 be vaccinated?**
Vaccination does not conflict with a previous COVID-19 infection. It actually enhances immunological memory; therefore no tests are necessary before vaccination. However, people who have been diagnosed COVID-19-positive do not need vaccination in the first phase of the vaccination campaign. Vaccination may be considered when data on the duration of immune protection are obtained.

**19. Can people with allergies be vaccinated with (Comirnaty) COVID-19 mRNA BNT162b2 vaccine?**
People with a history of severe anaphylactic reactions or severe allergy, or who are already aware that they are allergic to one of the components of the (Comirnaty) mRNA BNT162b2 vaccine should talk to their doctor before they are given the vaccine.

As with any vaccine, this vaccine should be administered under close medical supervision. People who experience a severe allergic reaction after receiving the first dose of the vaccine should not receive the second dose.
Allergic reactions (hypersensitivity) have been observed in people receiving the vaccine. Since the vaccine started being used in vaccination campaigns, very few cases of anaphylaxis (severe allergic reaction) have occurred.

**20. Can pregnant or breast-feeding women be vaccinated?**
There is limited experience with use of the vaccine in pregnant women. Animal studies do not indicate harmful effects with respect to pregnancy. The vaccine is not contraindicated and pregnant women should be vaccinated. When combined with other risk factors such as diabetes, cardiovascular disease and obesity, pregnancy may make women more at risk of severe COVID-19. The *Istituto Superiore di Sanità* (Health Institute) has a surveillance system in place for pregnant women in relation to COVID-19 that could provide useful information.
Although there are no studies on breast-feeding, no risk for breast-feeding is expected based on biological plausibility.
In general, the decision on whether to use the vaccine in pregnant or breast-feeding women should be made in close consultation with a healthcare professional after considering the benefits and risks.

**21. Can children be vaccinated with (Comirnaty) COVID-19 mRNA BNT162b2 vaccine?**
The vaccine is not currently recommended for children below 16 years of age. The European Medicines Agency (EMA) has agreed with the company on a plan to trial the vaccine in children at a later stage.

**22. Can people suffering from documented immunodeficiency or autoimmune diseases be vaccinated?**
There are currently no data available on the safety and efficacy of (Comirnaty) COVID-19 mRNA BNT162b2 vaccine in people suffering from autoimmune diseases. However, they were included in the initial trials. During clinical trials, no differences were observed concerning the onset of symptoms related to autoimmune or inflammatory diseases among subjects who had received the vaccine and those who had received placebo. People with autoimmune diseases showing no contraindications may receive the vaccine. There are limited data on immunocompromised people (people with weakened immune systems). Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.
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**23. Can people with chronic diseases, diabetes, tumours, and cardiovascular diseases be vaccinated?**
Since these are the people most at risk of developing a serious condition in case of SARS-CoV-2 contagion, they will be given priority for receiving the vaccine.

**24. Can people receiving anticoagulants be vaccinated?**

People receiving anticoagulant therapy have a generic contraindication to any injection. Therefore, the decision on whether to administer the vaccine in these people should be made by their doctor on a case-by-case basis, based on the risk of injection site bleeding.

**25. Can people who have recently received the influenza vaccine be vaccinated against COVID-19?**

There are still no data on the interference between COVID-19 vaccinations and other vaccinations. However, the nature of (Comirnaty) COVID-19 mRNA BNT162b2 vaccine suggests that it is unlikely that this vaccine interferes with other vaccines. However, a two-week interval can be observed as a precautionary measure.

**VACCINATION PROCEDURES**

**26. Who will administer the vaccine?**

Vaccination will be carried out by doctors and nurses of public vaccination centres, people who extensive vaccination experience and are trained in vaccination techniques. Furthermore, considering the specific features of this vaccine, healthcare professionals have received additional specific technical information on the preparation and administration of (Comirnaty) COVID-19 mRNA BNT162b2 vaccine.

**27. Who should I contact to be vaccinated?**

The vaccination campaign will be carried out at subsequent phases, with citizens being invited to get vaccinated according to an order of priority defined by the risk for people to become infected and develop the disease with serious consequences.

In the initial phase, priority will be given to healthcare professionals as well as staff and guests of retirement homes, and vaccinations will be carried out by vaccination centre staff in the 286 hospitals identified by the National COVID-19 Vaccination Plan. The same vaccination staff will provide vaccination at retirement homes.

**28. How much does vaccination cost?**

Vaccination is free for everyone.

**29. Is it possible to get vaccinated privately for a fee?**

No, currently available vaccines will only be used in the facilities identified by the Vaccination Plan and will not be available in pharmacies or on the private market. People are highly discouraged to try to obtain the vaccine by alternative channels or on the Internet. These channels give no guarantee on the quality of the product, which could be dangerous for the health as well as ineffective.

**30. Does the vaccine protect only the vaccinated person or their family too?**

The vaccine protects the individual, but if many people get vaccinated, the spread of the virus can be reduced to some extent, which will in turn protect all those people who cannot be vaccinated. Vaccination helps protect both the single person and the general population.

**31. Does vaccination allow to return to normalcy?**

Even if the effectiveness of the COVID-19 mRNA BNT162b2 vaccine is very high (over 90%), there will always be a proportion of vaccinated people who does not develop an immune response.

Moreover, it is still not known whether vaccination prevents just the manifestation of the disease or the spreading of the infection. This is why being vaccinated does not give a "go-ahead", but it is necessary to continue to adopt correct behaviours and measures to contain the risk of infection.

**32. Will there be vaccines for everyone?**

Through European procedures, the Italian government has booked the purchase of over two hundred million doses of COVID-19 vaccines from six different manufacturers. The person receiving the vaccine cannot freely choose which vaccine to receive: the vaccine available at the relevant time and place will be offered by the vaccination centres with equal safety and efficacy.

**33. How does the injection procedure work?**

During the handling of the vaccine and the injection, as with any intramuscular injection, there is a risk of contamination of the needles and syringes used due to environmental germs which, in case of incorrect procedure, could be injected together with the vaccine. If this happens, inflammation of the injection site of varying intensity may occur, up to purulent abscess.

To avoid this risk, aseptic techniques must be adopted, in particular, through minimizing environmental exposure of the syringe needles and bevel.

The procedure involves the use of a 3ml syringe to withdraw the dilution liquid to be injected into the multidose vial. Then, after dilution, withdrawal of 0.3 ml of vaccine and injection. This procedure is feasible with normal 3- or 5-ml standard syringes, for dilution, and 1 ml syringes (insulin type) for injection.

**34. What is the syringe Luer lock system?**

The Lock system provides for the permanent connection of the needle to the syringe, not allowing any separation for both the 3 ml and 1 ml syringes. The needles also have the same connection.

This system guarantees against:

1. The accidental separation of the needle from the 3 ml syringe during withdrawal and injection into the vial, as well as against separation of the needle from the syringe for the withdrawal and injection of the 0.3 ml of vaccine;

2. The reckless practice of leaving a needle stuck in the diluted vaccine vial to subsequently withdraw the 6 doses and inject them with different needles;

3. The reckless practice of withdrawing multiple doses of dilution (e.g., 2 * 1.8 = 3.6ml) using the same syringe for multiple vaccine vials;

4. The even more dangerous practice of withdrawing multiple doses of vaccine from the vaccine vial (e.g., 3 * 0.3 = 0.9 ml) by only changing the needle for multiple vaccinees.

Such practices are very dangerous due to exposure of needles and syringe bevels to microbial contamination and are already absolutely banned. However, in an extraordinary mass vaccination such as the one underway, errors cannot be ruled out, as already noted in some European countries.

The Luer lock system adds to the connection through simple insertion of the needle to the syringe, which is common to normal syringes, a connection through screwing breading which welds the

needle to the syringe, thus guaranteeing the prevention of the abovementioned errors, in that every needle and every syringe can be used only once.

**35. How to prevent risks for the healthcare operator?**

As any invasive health procedure, also vaccine injection shows a minimal risk due to handling of sharp objects such as needles: despite numerous national, European and WHO guidelines and regulations, the risk due to needle stick still displays significant numbers in Italy; therefore, it is deemed advisable to recall the Law Decree 19 February 2014 no. 19, providing regulations aimed at preventing these risks and namely Article 286 sexies, which expressly prohibits re-capping of the needle after injection, also providing for immediate disposal of the entire syringe, with the needle, in the special puncture-proof containers.

**36. What is the dose that needs to be inoculated and how many doses can be obtained per vial?**
The dose of vaccine to be administered to each person is 0.3 ml. This dose should be extracted, under aseptic conditions and using suitable precision syringes, from a vial of vaccine containing 2.25 ml after the planned dilution with 0.9% sodium chloride solution.
With the aim of using all the product available in each vial and avoiding any waste, AIFA, in accordance with the provisions of its Technical Scientific Committee, informs that, without prejudice to the need to guarantee the administration of the correct quantity of 0.3 ml to each vaccinated subject through the use of adequate syringes, it is possible to have at least 1 additional dose compared to the 5 doses declared in the Summary of Product Characteristics (SmPC).
Any residues from different vials, even those belonging to the same batch number, should not be mixed.

**37. Will only Italian citizens be vaccinated?**
According to the priority scheme defined in the Vaccination Plan, all people on the Italian territory, residents with or without a residence permit pursuant to Article 35 of Consolidated Law on Immigration, will be vaccinated.

**38. What documents are required for vaccination?**
A valid identity document and health card (*tessera sanitaria*) are required. It may be useful to show any health documentation that helps the vaccinating doctor to assess the person's physical condition.