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# Comirnaty (*COVID-19 mRNA Vaccine*)

An overview of Comirnaty, including its adapted vaccines, and why it is authorised in the EU

## What is Comirnaty and what is it used for?

Comirnaty is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people from the age of 6 months.

The originally authorised Comirnaty contains tozinameran, a messenger RNA (mRNA) molecule with instructions for producing a protein from the original strain of SARS-CoV-2, the virus that causes COVID-19.

As SARS-CoV-2 keeps evolving, Comirnaty has been adapted to target the most recent strains of the virus. This helps maintain protection against COVID-19.

Therefore, Comirnaty is also authorised as four adapted vaccines, with Comirnaty JN.1 and Comirnaty KP.2 being the most recent:

- Comirnaty Original/Omicron BA.4-5 contains tozinameran and famtozinameran, an mRNA molecule with instructions for producing a protein from the Omicron BA.4 and BA.5 subvariants of SARS-CoV-2;
- Comirnaty Omicron XBB.1.5 contains raxtozinameran, an mRNA molecule with instructions for producing a protein from the Omicron XBB.1.5 subvariant of SARS-CoV-2;
- Comirnaty JN.1 contains bretovameran, an mRNA molecule with instructions for producing a protein from the Omicron JN.1 subvariant of SARS-CoV-2;
- Comirnaty KP.2 contains an mRNA molecule with instructions for producing a protein from the Omicron KP.2 subvariant of SARS-CoV-2.

Comirnaty does not contain the virus itself and cannot cause COVID-19.

## How is Comirnaty used?

Adults and children from 5 years of age should receive a single dose injected into the muscle of the upper arm, irrespective of their previous vaccination history.

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Children from 6 months to 4 years of age who have completed a primary vaccination course or have had COVID-19 before should also receive a single dose, which can be injected into the muscle of the upper arm or thigh.

In children from 6 months to 4 years of age who have not completed a primary vaccination course and have not had COVID-19, the vaccine is given as three doses; the first two doses are given three weeks apart, followed by a third dose given at least 8 weeks after the second dose. The injections can be given in the muscles of the upper arm or thigh.

An additional dose may be given to people with a severely weakened immune system.

The vaccines should be used according to official recommendations issued at national level by public health bodies.

For more information about using Comirnaty, including information about the adapted vaccines, doses for different age groups, see the package leaflet or consult a healthcare professional.

## How does Comirnaty work?

Comirnaty works by preparing the body to defend itself against COVID-19. It contains a molecule called mRNA which has instructions for making the spike protein. This is a protein on the surface of SARS-CoV-2 which the virus needs to enter the body's cells and can differ between variants of the virus.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person's immune system will then recognise the protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with SARS-CoV-2, their immune system will recognise it and be ready to defend the body against it.

The mRNA from the vaccine is broken down after vaccination and removed from the body.

Adapted vaccines are expected to maintain protection against the virus as it evolves since they contain mRNA more closely matching circulating variants of the virus.

## What benefits of Comirnaty have been shown in studies?

A very large clinical trial showed that Comirnaty, given as a two-dose regimen, was effective at preventing COVID-19 in people from 12 years of age.

This main trial involved around 44,000 people aged 16 and above in total. Half received the vaccine and half were given a dummy injection. People did not know whether they received the vaccine or the dummy injection.

Efficacy in people aged 16 and above was calculated in over 36,000 participants (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 a dummy injection (162 cases out of 18,325 got COVID-19 symptoms). This means that the vaccine demonstrated a 95% efficacy in the trial.

The trial in people aged 16 years and older also showed around 95% efficacy in the participants at risk of severe COVID-19, including those with asthma, chronic lung disease, diabetes, high blood pressure or obesity.

The trial was extended to include 2,260 children aged 12 to 15 who had no sign of previous infection. It showed that the immune response to Comirnaty in this group was comparable to the immune response in the 16 to 25 age group (as measured by the level of antibodies against SARS-CoV-2). Around 2,000 children received either the vaccine or a placebo (a dummy injection), without knowing which one they were given. Of the 1,005 children receiving the vaccine, none developed COVID-19 compared with 16 children out of the 978 who received placebo. This means that, in this study, the vaccine was 100% effective at preventing COVID-19 (although the true rate could be between 75% and 100%).

Another study showed that an additional dose of Comirnaty increased the ability to produce antibodies against SARS-CoV-2 in organ transplant adult patients with severely weakened immune systems.

A study in children aged 5 to 11 showed that the immune response to Comirnaty given at a lower dose (10 micrograms) was comparable to that seen with the higher dose (30 micrograms) in 16- to 25-year-olds (as measured by the level of antibodies against SARS-CoV-2). Of the 1,305 children receiving the vaccine, three developed COVID-19 compared with 16 out of the 663 children who received placebo. This means that, in this study, the vaccine was 90.7% effective at preventing symptomatic COVID-19 (although the true rate could be between 67.7% and 98.3%).

A main study in children from 6 months to 4 years of age evaluated the immune response triggered by the vaccine (given as 3 injections) by measuring the level of antibodies against SARS-CoV-2. The study showed that the immune response to the lower dose of Comirnaty (3 micrograms) was comparable to that seen with the higher dose (30 micrograms) in 16- to 25-year-olds.

Additional data showed that subsequent doses, including boosters, lead to a rise in levels of antibodies against SARS-CoV-2.

Available data also indicate that vaccines adapted to target circulating strains of the virus are expected to elicit a strong immune response against these strains.

## Can children be vaccinated with Comirnaty?

The originally authorised Comirnaty and the adapted vaccines are authorised for adults and children from 6 months of age.

## Can immunocompromised people be vaccinated with Comirnaty?

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.

Severely immunocompromised people may be given an additional dose of Comirnaty as part of their primary vaccination.

## Can pregnant or breast-feeding women be vaccinated with Comirnaty?

Comirnaty can be used during pregnancy. A large amount of data from pregnant women vaccinated with Comirnaty during the second or third trimester of their pregnancy has been analysed and showed no increase in pregnancy complications. Although data in the first trimester of pregnancy are more limited, no increased risk of miscarriage was seen.

Comirnaty can also be used during breast-feeding. Data from women who were breast-feeding after vaccination have not shown a risk of adverse effects in breastfed babies.

No data are currently available regarding the use of the adapted vaccines in pregnant or breastfeeding women. Based on the data available for the originally authorised Comirnaty, Comirnaty Original/Omicron BA.4-5, Comirnaty Omicron XBB.1.5, Comirnaty JN.1 and Comirnaty KP.2 can also be used during pregnancy and breast-feeding.

## Can people with allergies be vaccinated with Comirnaty?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet must not receive the vaccine.

Allergic reactions (hypersensitivity) have been seen in people receiving the vaccine. A very small number of cases of anaphylaxis (severe allergic reaction) have occurred. Therefore, as for all vaccines, Comirnaty, including its adapted vaccines, should be given under close medical supervision, with the appropriate medical treatment available. People who have a severe allergic reaction when they are given a dose of one of the Comirnaty vaccines should not receive subsequent doses.

## How well does Comirnaty work for people of different ethnicities and genders?

The main Comirnaty trial included people of different ethnicities and genders. Efficacy of around 95% in the main trial was maintained across genders and ethnic groups.

## What are the risks associated with Comirnaty?

For the full list of side effects and restrictions with Comirnaty, see the package leaflet.

The most common side effects with Comirnaty are usually mild or moderate and get better within a few days after vaccination. These include pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills, fever and diarrhoea. They may affect more than 1 in 10 people. In children aged 6 to 23 months, the most common side effects also include irritability, sleepiness, loss of appetite, tenderness or redness at the injection site and fever. The most common side effects in children 2 to 4 years of age include pain or redness at the injection site, tiredness and fever.

Redness at the injection site, enlarged lymph nodes, nausea and vomiting may occur in up to 1 in 10 people. Itching at the injection site, pain in the arm where the vaccine was injected, enlarged lymph nodes, difficulty sleeping, feeling unwell, decreased appetite, lethargy (lack of energy), hyperhidrosis (excessive sweating), night sweats, asthenia (weakness), and allergic reactions (such as rash, itching, itchy rash, and rapid swelling under the skin) are uncommon side effects (affecting less than 1 in 100 people). Weakness in muscles on one side of the face (acute peripheral facial paralysis or palsy) occurs in less than 1 in 1,000 people.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) may occur in up to 1 in 10,000 people.

Very few cases of extensive swelling of the vaccinated arm, swelling of the face in people with a history of injections with dermal fillers (soft, gel-like substances injected under the skin), erythema multiforme (red patches on the skin with a dark red centre and paler red rings) paraesthesia (unusual feeling in the skin, such as tingling or a crawling feeling) and hypoesthesia (decreased feeling or sensitivity in the skin) have occurred. Allergic reactions have also occurred with Comirnaty, including a very small number of cases of severe allergic reactions (anaphylaxis).

The safety of the adapted vaccines is similar to that of the originally authorised Comirnaty vaccine.

## Why is Comirnaty authorised in the EU?

Data show that Comirnaty causes the production of antibodies against SARS-CoV-2 that can protect against COVID-19. The main trials of Comirnaty showed that the vaccine has a high efficacy in all age groups. Most side effects are mild to moderate in severity and resolve within a few days.

The Agency therefore decided that the benefits of Comirnaty, including its adapted vaccines, are greater than its risks and that it can be authorised for use in the EU.

Comirnaty was originally given 'conditional authorisation' because there was more evidence to come about the vaccine. The company has provided comprehensive information, including data regarding its safety, efficacy, and how well Comirnaty prevents severe disease. In addition, the company has completed all requested studies on the pharmaceutical quality of the vaccine. As a result, the conditional authorisation has been switched to a standard one.

## What measures are being taken to ensure the safe and effective use of Comirnaty?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Comirnaty have been included in the summary of product characteristics and the package leaflet.

A risk management plan (RMP) is also in place and contains important information about the vaccines' safety, how to collect further information and how to minimise any potential risks.

Safety measures for Comirnaty are implemented in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets Comirnaty provides regular reports on the safety and efficacy of the vaccine.

As for all medicines, data on the use of Comirnaty are continuously monitored. Suspected side effects are carefully evaluated and any necessary action taken to protect patients.

## Other information about Comirnaty

Comirnaty received a conditional marketing authorisation valid throughout the EU on 21 December 2020. This was switched to a standard marketing authorisation on 10 October 2022.

More information about the COVID-19 vaccines is available on the COVID-19 vaccines key facts page.

Further information on Comirnaty, including its adapted vaccines, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/comirnaty

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