EMA/564423/2021
EMEA/H/C/005735

Comirnaty (*COVID-19 mRNA vaccine [nucleoside modified]*)

An overview of Comirnaty 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 aged 12 years and older.

Comirnaty contains a molecule called messenger RNA (mRNA) with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID-19. Comirnaty does not contain the virus itself and cannot cause COVID-19.

How is Comirnaty used?

Comirnaty is given as two injections, usually into the muscle of the upper arm, 3 weeks apart.

An additional dose may be given to people with a severely weakened immune system, at least 28 days after their second dose.

A booster dose may be given at least 6 months after the second dose for people aged 18 years and older. At national level, public health bodies may issue official recommendations, taking into account emerging effectiveness data and the limited safety data.

For more information about using Comirnaty, 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 the SARS-CoV-2 virus which the virus needs to enter the body's cells.

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 this 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 virus, their immune system will recognise it and be ready to defend the body against it.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination.

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.

The 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. 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). The efficacy of Comirnaty was calculated in close to 2,000 children from 12 to 15 who had no sign of previous infection. These 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 to 16 children out of the 978 who received the dummy injection. 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 patients with severely weakened immune systems.

Further data showed a rise in antibody levels when a booster dose was given after the second dose in people from 18 to 55 years old with a normal immune system.

Can people who have already had COVID-19 be vaccinated with Comirnaty?

There were no additional side effects in the 545 people who received Comirnaty in the trial and had previously had COVID-19.

There were not enough data from the trial to conclude on how well Comirnaty works for people who have already had COVID-19.

Can Comirnaty reduce transmission of the virus from one person to another?

The impact of vaccination with Comirnaty on the spread of the SARS-CoV-2 virus in the community is not yet known. It is not yet known how much vaccinated people may still be able to carry and spread the virus.

How long does protection from Comirnaty last?

It is not currently known how long protection given by Comirnaty lasts. The people vaccinated in the clinical trial will continue to be followed for 2 years to gather more information on the duration of protection.

Can children be vaccinated with Comirnaty?

Comirnaty is not currently authorised for children below 12 years of age.

Can immunocompromised people be vaccinated with Comirnaty?

There are limited data on immunocompromised people. 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, at least 28 days after their second dose.

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

Animal studies do not show any harmful effects in pregnancy, however data on the use of Comirnaty during pregnancy are very limited. Although there are no studies on breast-feeding, no risk for breast-feeding is expected.

The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks.

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 should 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 since the vaccine started being used in vaccination campaigns. Therefore, as for all vaccines, Comirnaty should be given under close medical supervision, with the appropriate medical treatment available. People who have a severe allergic reaction when they are given the first dose of Comirnaty should not receive the second dose.

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

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

What are the risks associated with Comirnaty?

The most common side effects with Comirnaty were usually mild or moderate and got better within a few days after vaccination. These included pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills, fever and diarrhoea. They affected more than 1 in 10 people.

Redness at the injection site, nausea and vomiting occurred in less than 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) were uncommon side effects (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.

A very small number of cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) have occurred with Comirnaty. Allergic reactions have also occurred with Comirnaty, including a very small number of cases of severe allergic reactions (anaphylaxis). As for all vaccines, Comirnaty should be given under close supervision with appropriate medical treatment available.

Why is Comirnaty authorised in the EU?

Comirnaty offers a high level of protection against COVID-19 which is a critical need in the current pandemic. The main trial showed that the vaccine has a 95% efficacy. Most side effects are mild to moderate in severity and are gone within a few days.

The Agency therefore decided that Comirnaty's benefits are greater than its risks and that it can be authorised for use in the EU.

Comirnaty has been granted a conditional marketing authorisation. This means that there is more evidence to come about the vaccine (see below), which the company is required to provide. The Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Comirnaty?

As Comirnaty received a conditional marketing authorisation, the company that markets Comirnaty will continue to provide results from the main trial, which is ongoing for 2 years. This trial and additional studies will provide information on how long protection lasts, how well the vaccine prevents severe COVID-19, how well it protects immunocompromised people, pregnant women, and whether it prevents asymptomatic cases.

In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will also give more information on the vaccine's long-term safety and benefit in the general population.

The company will also carry out studies to provide additional assurance on the pharmaceutical quality of the vaccine as the manufacturing continues to be scaled up.

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) for Comirnaty is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks.

Safety measures will be implemented for Comirnaty 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 will provide monthly safety reports.

As for all medicines, data on the use of Comirnaty are continuously monitored. Suspected side effects reported with Comirnaty 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.

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

This overview was last updated in 10-2021.