EMADOC-1700519818-2486748
EMEA/H/C/006058

Bimervax (*COVID-19 vaccine (recombinant, adjuvanted)*)

An overview of Bimervax and why it is authorised in the EU

What is Bimervax and what is it used for?

Bimervax is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 12 years and older.

The active substance in Bimervax is a protein produced in the laboratory that consists of part of the SARS-CoV-2 (the virus that causes COVID-19). In the originally authorised Bimervax, this protein was designed to match the protein from the Alpha and Beta variants. As SARS-CoV-2 keeps evolving, Bimervax has been adapted to target more recent strains of the virus. This helps maintain protection against COVID-19.

Three versions of Bimervax are currently authorised, with Bimervax LP.8.1 being the most recent:

- Bimervax original which targets the Alpha and Beta variants of SARS-CoV-2;
- Bimervax XBB.1.16 which targets the XBB.1.16 variant of SARS-CoV-2;
- Bimervax LP.8.1 which targets the LP.8.1 variant of SARS-CoV-2.

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

How is Bimervax used?

Bimervax is given as a single injection, usually in the muscle of the upper arm.

The originally authorised Bimervax is given as a booster at least 6 months after a previous mRNA COVID-19 vaccine or after a previous booster with Bimervax.

The adapted Bimervax XBB.1.16 and LP.8.1 vaccines can be given irrespective of previous vaccination history. In people who have been previously vaccinated against COVID-19, they should be given at least 6 months after the last dose of a COVID-19 vaccine.

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

For more information about using Bimervax, see the package leaflet or consult a healthcare professional.

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How does Bimervax work?

Bimervax works by preparing the body to defend itself against COVID-19. The vaccine contains a protein produced in the laboratory that consists of part of the SARS-CoV-2 spike protein. It also contains an 'adjuvant', a substance to help strengthen the immune response to the vaccine.

When a person is given the vaccine, their immune system will identify the combined protein as foreign and produce natural defences — antibodies and T cells — against it. If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the spike protein on the virus and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, prevent its entry into the body's cells and destroy infected cells.

Adapted vaccines help maintain protection by including a protein that more closely matches circulating variants of the virus.

What benefits of Bimervax have been shown in studies?

The benefits of the originally authorised Bimervax were assessed in a study which compared the immune response induced by Bimervax with that induced by the authorised mRNA vaccine Comirnaty, which targets the original variant of SARS-CoV-2 (Wuhan).

The study involved 765 adults who had previously completed primary vaccination with 2 doses of Comirnaty and who were subsequently given a booster dose of either Bimervax or Comirnaty. Although Bimervax triggered the production of lower levels of antibodies against the original variant of SARS-CoV-2 than Comirnaty, it led to higher levels of antibodies against the Beta and Omicron variants and comparable levels against the Delta variant.

Supportive data were provided from a study that involved 36 adolescents aged 16 to 17 years old, with immune response data available for 11 of them. This study found that Bimervax given as a booster produced an adequate immune response in these adolescents, with antibody production comparable to that seen in adults who received Bimervax.

Data were also provided from an ongoing study that involved 240 adolescents aged 12 to 17 years old, with immune response data available for 88 of them. Of these 88 adolescents, 61 were aged between 12 to 15 years. These data showed that when Bimervax was given as a booster, the immune response it produced in these adolescents was comparable to that seen in adolescents aged 16 and 17 years.

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

Can children be vaccinated with Bimervax?

Bimervax is authorised in adolescents aged 12 years and older. It is not recommended in younger children. EMA has agreed with the company on a plan to assess the vaccine in younger children at a later stage.

Can immunocompromised people be vaccinated with Bimervax?

There are limited data on the use of Bimervax in 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. Severely immunocompromised people may be given additional doses of Bimervax.

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

Animal studies do not show any harmful effects in pregnancy; however, no data are available yet on the use of Bimervax during pregnancy.

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.

Although there are no studies on breast-feeding, no risk for breast-feeding is expected.

Can people with allergies be vaccinated with Bimervax?

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) may occur in people receiving the vaccine. Therefore, as for all vaccines, Bimervax should be given under close medical supervision, with the appropriate medical treatment available.

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

The immune response triggered by the vaccine in the main study was maintained across genders. There is no reason to suggest that the immune response induced by Bimervax will vary across ethnicities.

What are the risks associated with Bimervax?

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

In adults, the most common side effects with Bimervax (which may affect more than 1 in 10 people) include pain at the injection site, headache, tiredness and muscle pain.

Lymphadenopathy (enlarged lymph nodes), diarrhoea, vomiting, nausea (feeling sick), fever, pain in the armpits, and reddening, hardness or swelling at the injection site may affect less than 1 in 10 people.

Dizziness, sleepiness, itching, joint pain, weakness, chills, feeling generally unwell and itching at the injection site may affect less than 1 in 100 people.

Paraesthesia (unusual feeling in the skin, such as tingling or a crawling feeling), odynophagia (painful swallowing), abdominal pain, hypoaesthesia (reduced sensation to touch, pain and temperature), rash, itchy rash, cold sweats, bruising and hypersensitivity at the injection site, and erythema (reddening of the skin) may affect less than 1 in 1000 people.

In adolescents, the most common side effects with Bimervax (which may affect more than 1 in 10 people) include pain at the injection site, headache, tiredness and malaise (feeling generally unwell).

One case of pericarditis (inflammation of the membrane around the heart) was seen in the clinical studies.

Allergic reactions may occur with Bimervax. As for all vaccines, Bimervax should be given under close supervision with appropriate medical treatment available.

The safety of Bimervax adapted vaccines are comparable to that of the originally authorised vaccine.

Why is Bimervax authorised in the EU?

Based on data comparing the immune response triggered by the originally authorised Bimervax given as a booster with that triggered by an authorised mRNA COVID-19 vaccine given as a booster, the European Medicines Agency concluded that the originally authorised Bimervax is expected to be at least as effective as the comparator at restoring protection against COVID-19 in people aged 16 years and older.

Data in younger adolescents showed that Bimervax is expected to have comparable effectiveness in adolescents aged 12 to 15 years and in adolescents aged 16 or 17 years.

Data also show that versions of Bimervax adapted to target XBB.1.16 or LP.8.1 cause the production of antibodies against SARS-CoV-2 that can protect against COVID-19.

The safety profile of Bimervax is comparable to that of other COVID-19 vaccines. The most common side effects are usually mild to moderate and clear within a few days after vaccination.

The Agency therefore decided that the benefits of Bimervax, including its adapted vaccines, are greater than its risks and that they can be recommended for authorisation in the EU.

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

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

A risk management plan (RMP) for Bimervax 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 for Bimervax and its adapted vaccines 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 Bimervax provides regular reports on the safety and efficacy of the vaccine.

As for all medicines, data on the use of Bimervax and its adapted vaccines are continuously monitored. Suspected side effects reported with Bimervax are carefully evaluated and any necessary action taken to protect patients.

Other information about Bimervax

Bimervax received a marketing authorisation valid throughout the EU on 30 March 2023.

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

This overview was last updated in 10-2025.