EMA/56169/2025
EMEA/H/C/006058

Bimervax (*COVID-19 vaccine (recombinant, adjuvanted) / selvacovatein / damlecovatein*)

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 16 years and older.

The originally authorised Bimervax contains the active substance selvacovatein, a protein produced in the laboratory that consists of part of the SARS-CoV-2 (the virus that causes COVID-19) spike protein from the Alpha and Beta strains.

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.

The adapted Bimervax targeting the XBB.1.16 strain contains the active substance damlecovatein, a protein produced in the laboratory that consists of part of the SARS-CoV-2 spike protein from the XBB.1.16 strain.

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.

Bimervax XBB.1.16 is given irrespective of previous vaccination history. It should be given at least 6 months after the last dose of a COVID-19 vaccine in people who have been previously vaccinated against COVID-19.

The vaccines 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.

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

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 are expected to help maintain protection against the virus as it evolves, since they contain a spike protein more closely matching circulating variants of the virus. Nevertheless, the originally authorised and adapted Bimervax vaccines may not match, and be effective against, circulating strains.

What benefits of Bimervax have been shown in studies?

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

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 strain 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 an ongoing study that included 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.

Laboratory studies showed that Bimervax XBB.1.16 is able to trigger an adequate immune response against the XBB.1.5 and XBB.1.16 strains. In addition, a study involving almost 900 people found that booster vaccination with Bimervax XBB.1.16 produced a higher immune response against the XBB.1.16 strain to that seen after booster vaccination with an authorised COVID-19 vaccine targeting the XBB.1.5 strain. Based on these data, Bimervax XBB.1.16 is expected to trigger an adequate immune response against the XBB.1.16 strain.

Can children be vaccinated with Bimervax?

Currently, Bimervax is not recommended for people below 16 years of age. EMA has agreed with the company on a plan to assess the vaccine in children at a later stage.

Can immunocompromised people be vaccinated with Bimervax?

Bimervax has not been studied 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.

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.

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.

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 XBB.1.16 is 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.

The adapted vaccine Bimervax XBB.1.16 also causes the production of antibodies against SARS-CoV-2 that can protect against the XBB.1.16 strain, which was circulating at the time of the study. At the time of approval, more recent strains were in circulation. However, the agency considered the data provided for the evaluation of Bimervax XBB.1.16 useful for the development and evaluation of future adapted Bimervax vaccines.

The safety profiles of both the originally authorised Bimervax and Bimervax XBB.1.16 are 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 vaccine, are greater than its risks and that it 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 vaccine 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 vaccine 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 02-2025.