30 March 2023
EMA/141306/2023
EMEA/H/C/006058

Bimervax

SARS-CoV-2 virus recombinant protein receptor binding domain (RBD) fusion heterodimer (B.1.351 and B.1.1.7 strains)

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. It can be used as a booster in people who have previously received an mRNA COVID-19 vaccine.

Bimervax contains a protein produced in the laboratory that consists of part of the SARS-CoV-2 spike protein from the Alpha and Beta virus variants.

Detailed information about this vaccine is available in the product information, which includes the package leaflet.

How is Bimervax used?

Bimervax is given as an injection, usually in the muscle of the upper arm. It is given as a booster at least 6 months after a previous mRNA COVID-19 vaccine.

Arrangements for the supply of the vaccine will be the responsibility of national authorities.

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

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 from the Alpha and Beta virus variants. 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

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

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.

What benefits of Bimervax have been shown in studies?

The benefits of 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.

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?

The most common side effects with Bimervax (which may affect more than 1 in 10 people) are 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.

Insomnia (difficulty sleeping), dizziness, sleepiness, odynophagia (painful swallowing), abdominal pain, itching, joint pain, weakness, chills, feeling generally unwell and itching and sensitivity 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), hypoaesthesia (reduced sensation to touch, pain and temperature), rash, itchy rash, cold sweats, erythema (reddening of the skin), back pain and injection site bruising 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.

Why has EMA recommended the authorisation of Bimervax?

Based on data comparing the immune response triggered by Bimervax with that triggered by an authorised mRNA COVID-19 vaccine, EMA concluded that 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 safety profile of Bimervax is comparable to that of other COVID-19 vaccines. The most common side effects seen with Bimervax were usually mild to moderate and cleared within a few days after vaccination.

The Agency therefore decided that Bimervax's benefits 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 will be implemented for Bimervax in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed.

As for all medicines, data on the use of Bimervax 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 was recommended by EMA's human medicines committee (CHMP) on 30 March 2023 for a marketing authorisation valid throughout the EU. The European Commission will issue a decision shortly.

Detailed recommendations for the use of this product are described in the product information, which will be available in all official European Union languages after a decision on the marketing authorisation has been issued by the European Commission.