Package leaflet: Information for the user

BIMERVAX®

COVID-19 vaccine (recombinant, adjuvanted)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What BIMERVAX is and what it is used for

BIMERVAX is a vaccine used to prevent COVID-19 caused by the SARS-CoV-2 virus.

BIMERVAX is given to individuals 16 years of age and older who have previously received a mRNA COVID-19 vaccine.

The vaccine stimulates the immune system (the body's natural defences) to produce specific antibodies that work against the virus, giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you receive BIMERVAX

BIMERVAX should not be given
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before receiving BIMERVAX if:
- you have ever had a severe or life-threatening allergic reaction after receiving any other vaccine injection;
- you have ever fainted following any needle injection;
- you have a high temperature (over 38 °C) or severe infection. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold;
- you have bleeding problems, you bruise easily or you use a medicine to prevent blood clots (anticoagulant medicine);
- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants, or cancer medicines).

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist, or nurse before you are given BIMERVAX.

As with any vaccine, BIMERVAX may not fully protect all those who receive it, and it is not known how long you will be protected.

Children and adolescents
BIMERVAX is not recommended for children aged below 16 years. Currently, there is no information available on the use of BIMERVAX in children younger than 16 years of age.

Other medicines and BIMERVAX
Tell your doctor, pharmacist, or nurse if you are taking, have recently taken, or might take any other medicines or vaccines.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist, or nurse for advice before you receive this vaccine.

Driving and using machines
Some of the side effects of BIMERVAX listed in section 4 (Possible side effects) may temporarily reduce your ability to drive and use machines. Wait until any effects of the vaccine have worn off before you drive or use machines.

BIMERVAX contains sodium and potassium
This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

This vaccine contains less than 1 mmol potassium (39 milligrams) per 0.5 mL dose, that is to say, essentially 'potassium-free'.

3. How BIMERVAX is given

BIMERVAX will be given to you as 0.5 mL injections into a muscle of your upper arm.

It is recommended that you receive BIMERVAX as a single dose at least 6 months after a previous vaccination series with mRNA COVID-19 vaccine.

After the injection, your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

If you have any further questions on the use of BIMERVAX, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Most of the side effects occur within 3 days of getting the vaccine and go away within a few days of appearing. If symptoms persist, contact your doctor, pharmacist or nurse.

Get urgent medical attention if you get symptoms of a severe allergic reaction shortly after vaccination. Such symptoms may include:
- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- itchy swelling under the skin (hives) or rash
- feeling sick (nausea) or vomiting
- stomach pain

The following side effects may occur with BIMERVAX:

Very common (may affect more than 1 in 10 people)
- headache
- pain where the injection is given
- feeling very tired (fatigue)
- muscle pain

Common (may affect up to 1 in 10 people)
- redness, swelling or tenderness where the injection is given
- feeling sick (nausea) or getting sick (vomiting)
- diarrhoea
- fever
- enlarged lymph nodes
- axillary pain

Uncommon (may affect up to 1 in 100 people)
- chills or feeling feverish
- insomnia
- dizziness
- itching where the injection is given
- hipersensitivity where the injection is given
- joint pain
- feeling weak or lack of energy
- feeling sleepy
- abdominal pain
- itchy skin
- pain when swallowing
- generally feeling unwell

Rare (may affect up to 1 in 1 000 people)
- cold sweating
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling of sensitivity, especially in the skin (hypoaesthesia)
- allergic reactions such as hives, rash or itching
- Back pain
- Bruise where the injection is given

Not known (cannot be estimated from available data, based on a single case during clinical trials)
- Inflammation of the lining outside the heart (pericarditis), which can result in breathless, palpitations or chest pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V and include batch/Lot number if available. By reporting side effects, you can help provide more information on the safety of this vaccine.

5. How to store BIMERVAX

Keep this medicine out of the sight and reach of children.

Your doctor, pharmacist, or nurse is responsible for storing this vaccine and disposing of any unused product correctly. The following information about storage, expiry, use and handling as well as disposal is intended for healthcare professionals.

Do not use this vaccine after the expiry date which is stated on the label after EXP.

Store in a refrigerator (2 ºC – 8 ºC). Do not freeze. Keep vials in outer carton in order to protect from light.

Store the vaccine at 2 ºC - 8 ºC during the immunization session or within six hours after opening. Opened multi-dose vaccine vials should be discarded at the end of the immunization session, or within six hours after opening, whichever comes first.

Information on handling are described in the section intended for healthcare professionals at the end of the package leaflet.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What BIMERVAX contains

- One dose (0.5 mL) contains 40 micrograms of SARS-CoV-2 virus recombinant spike (S) protein RBD fusion heterodimer* (B.1.351 and B.1.1.7 strains) adjuvanted with SQBA.

*Produced by recombinant DNA technology using a plasmid expression vector in a CHO cell line.

- SQBA is included in this vaccine as an adjuvant to accelerate and improve the protective effects of the vaccine. SQBA contains per 0.5 mL dose: squalene (9.75 mg), polysorbate 80 (1.18 mg), sorbitan trioleate (1.18 mg), sodium citrate (0.66 mg), citric acid (0.04 mg) and water for injections.

- The other ingredients (excipients) are: disodium phosphate dodecahydrate, potassium dihydrogen phosphate, sodium chloride, potassium chloride and water for injections. BIMERVAX contains potassium and sodium (see section 2).

What BIMERVAX looks like and contents of the pack

The vaccine is a white homogeneous emulsion for injection.

Multidose vial

5 mL of emulsion is provided in a vial with a rubber stopper and a plastic flip-off top.

Each vial contains 10 doses of 0.5 mL.

Pack size: 10 multidose vials.

Single dose vial

0.5 mL of emulsion is provided in a vial with a rubber stopper and a plastic flip-off top.

Pack sizes: 20, 10 and 5 single dose vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Hipra Human Health, S.L.U.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

Manufacturer

Laboratorios Hipra S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

Scan the code with a mobile device to get the package leaflet in different languages.

Or visit the URL: www.hipracovidvaccine.com

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

Administer BIMERVAX intramuscularly, preferably into the deltoid muscle of the upper arm.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions and administration

Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

This vaccine should be handled by a healthcare professional using aseptic techniques to ensure the sterility of each dose.

Preparation for use
- The vaccine comes ready to use.
- Unopened vaccine should be stored at 2 °C to 8 °C and kept within the outer carton to protect from light.

- Immediately prior to use, remove the vaccine vial from the outer carton.
- After first puncture of the multidose vial, record the discard date and time (6 hours after first puncture) on the designated area of the vial label.

Inspect the vial
- Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake.
- Each vial contains a white and homogeneous emulsion.
- Visually inspect the contents of the vaccine particulate matter and/or discolouration prior to administration. Do not administer the vaccine if either are present.

Administer the vaccine
- An overfill is included per vial to ensure that a maximum of ten (10) doses (multidose vial) or one (1) dose (single dose vial) of 0.5 mL each can be extracted. Discard any remaining vaccine in the multidose vial after 10 doses have been extracted.
- Each 0.5 mL dose is withdrawn into a sterile needle and sterile syringe to be administered by intramuscular injection, preferably in the deltoid muscle of the upper arm.
- Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.
- Do not pool excess vaccine from multiple vials.

Discard
- Discard this vaccine if not used within 6 hours after first puncture of the multidose vial.

Disposal
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Vaccine Vial Monitors (VVMs) are on the label of BIMERVAX. This is a time-temperature sensitive that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. Its color will change progressively. As long as the color of this square is lighter than the color of the outer circle, then the vaccine can be used. As soon as the color of the central square is the same color as the outer circle or of a darker color than the outer circle, then the vial should be discarded.