Package leaflet: Information for the user

BIMERVAX® LP.8.1 emulsion for injection
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 effect you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you recieve 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 LP.8.1 is and what it is used for

BIMERVAX LP.8.1 is a vaccine used to prevent COVID-19 caused by the SARS-CoV-2 virus.

BIMERVAX LP.8.1 is given to individuals 12 years of age and older.

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 LP.8.1

BIMERVAX LP.8.1 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 LP.8.1 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 LP.8.1.

As with any vaccine, BIMERVAX LP.8.1 may not fully protect all those who receive it, and it is not known how long you will be protected.

Children
BIMERVAX LP.8.1 is not recommended for children aged below 12 years. Currently, there is no information available on the use of BIMERVAX LP.8.1 in children younger than 12 years of age.

Other medicines and BIMERVAX LP.8.1
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 LP.8.1 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 LP.8.1 contains sodium and potassium and polysorbate
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 mg) per 0.5 mL dose, that is to say, essentially 'potassium-free'.

This vaccine contains 1.18 mg of polysorbate 80 in each dose. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How BIMERVAX LP.8.1 is given

Individuals 12 years of age and older
BIMERVAX LP.8.1 will be given to you as 0.5 mL injection into a muscle of your upper arm.

It is recommended that you receive BIMERVAX LP.8.1 as a single dose at least 6 months after a previous dose of a 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 LP.8.1, ask your doctor, pharmacist or nurse.

Immunocompromised individuals
If your immune system does not work properly additional doses may be administered in line with official recommendations.

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 LP.8.1:

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
- dizziness
- itching where the injection is given
- joint pain
- feeling weak or lack of energy
- feeling sleepy
- itchy skin
- 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)
- abdominal pain
- pain when swallowing
- allergic reactions such as hives, rash or itching
- bruise where the injection is given
- hypersensitivity 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this vaccine.

5. How to store BIMERVAX LP.8.1

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. The expiry date refers to the last day of that month.

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

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 LP.8.1 contains

- One dose (0.5 mL) contains 40 micrograms of SARS-CoV-2 virus recombinant spike (S) protein RBD fusion homodimer* (Omicron LP.8.1 – LP.8.1 strain) 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 LP.8.1 contains potassium, sodium and polysorbate (see section 2).

What BIMERVAX LP.8.1 looks like and contents of the pack

The vaccine is a white homogeneous emulsion for injection.

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

Each single dose vial contains 1 dose of 0.5 mL

Pack sizes: 1, 10 or 20 single dose vials.

Marketing Authorisation Holder and Manufacturer

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

Local Representative in UK
Accord-UK Ltd
Whiddon Valley, Barnstaple, Devon, EX32 8NS
United Kingdom

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Other sources of information

For more information, scan or visit the URL: www.hipracovidvaccine.com

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The following information is intended for healthcare professionals only:

Administer BIMERVAX LP.8.1 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.

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

Administer the vaccine
- An overfill is included in each vial to ensure that one dose of 0.5 mL can be extracted. Discard any remaining vaccine in the vial.
- One 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.

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