PACKAGE LEAFLET

Package leaflet: Information for the user

COVID-19 Vaccine Valneva
Suspension for injection
COVID-19 vaccine (inactivated, adjuvanted, adsorbed**)**

▼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 COVID-19 Vaccine Valneva is and what it is used for

COVID-19 Vaccine Valneva is a vaccine used to prevent COVID-19 caused by SARS-CoV-2.

COVID-19 Vaccine Valneva is given to adults aged between 18 and 50 years.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that works against the virus so giving protection against COVID-19.

None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you are given COVID-19 Vaccine Valneva

COVID-19 Vaccine Valneva must not be given
- if you are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6).

Warnings and precautions
Tell your doctor, pharmacist or nurse before you are given COVID-19 Vaccine Valneva if:
- you have previously had a severe, life-threatening allergic reaction after any other vaccine injection or after you were given COVID-19 Vaccine Valneva in the past
- you have ever fainted following any needle injection or if you have anxiety related to injections
- you have a severe illness or infection with high fever. You can have your vaccination if you have a mild fever or upper airway infection like a cold
- you have a problem with bleeding, you bruise easily or if you use a medicine to prevent blood clots
- you have a weakened immune system because of a disease such as HIV infection or you are taking medicines, such as corticosteroid, that affect your immune system

Two doses of COVID-19 Vaccine Valneva are necessary to start protecting you. As with any vaccine, even the 2-dose vaccination course may not fully protect all those who receive it and it is not known how long you will be protected. No data are currently available in individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses.

Children and adolescents
COVID-19 Vaccine Valneva is not recommended for children and adolescents aged below 18 years. Currently there is not enough information available on the use of COVID-19 Vaccine Valneva in children and adolescents younger than 18 years of age.

Other medicines and COVID-19 Vaccine Valneva
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines or other vaccines.

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

Driving and using machines
Some of the side effects of COVID-19 Vaccine Valneva listed in section 4 may temporarily affect your ability to drive and use machines. Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

COVID-19 Vaccine Valneva contains potassium and sodium
This vaccine contains potassium, less than 1 mmol (39 mg) per 0.5 mL dose, i.e. essentially 'potassium-free'.
This vaccine contains less than 1 mmol sodium (23 mg) per 0.5 mL dose, that is to say essentially 'sodium-free'.

3. How COVID-19 Vaccine Valneva is given

COVID-19 Vaccine Valneva is given as an injection of 0.5 mL into a muscle of your upper arm.

You will receive 2 injections of the same vaccine, given at least 28 days apart to complete the vaccination course.

If you miss an appointment for your second injection of COVID-19 Vaccine Valneva, it is important that you return for your second injection as you are not protected against COVID-19.

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

4. Possible side effects

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

The following side effects may occur with COVID-19 Vaccine Valneva

Very common side effects (may affect more than 1 in 10 people)
- headache
- nausea
- vomiting
- muscle pain
- tiredness
- injection site pain

Common side effects (may affect up to 1 in 10 people)
- injection site: itching, hardening, swelling, redness
- fever

Uncommon side effects (may affect up to 1 in 100 people)
- enlarged lymph nodes
- dizziness
- deep unresponsiveness (lethargy)
- decreased or abnormal sensation of skin (for example pins and needles)
- taste disturbance
- diarrhoea
- belly pain
- chills
- excessive sweating
- rash
- pain in leg or arm
- joint pain
- muscle cramps

Rare side effects (may affect up to 1 in 1,000 people)
- hives

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.

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. When completing a report please include the vaccine brand and batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store COVID-19 Vaccine Valneva

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

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

Information about storage, expiry, and use and handling are described in the section intended for healthcare professionals at the end of the package leaflet.

6. Contents of the pack and other information

What COVID-19 Vaccine Valneva contains

The active substance is a highly purified whole virus SARS-CoV-2 antigen[1], inactivated[2] and adjuvanted with CpG 1018[3] in combination with aluminium hydroxide[4].
One multi-dose vial contains 10 single doses of 0.5 mL.
One dose (0.5 mL) contains no less than 25 Antigen Units (AU) of inactivated SARS-CoV-2.

[1] Produced on Vero cells
[2] Inactivated with beta-propiolactone
[3] 1 mg CpG 1018 (cytosine phospho-guanine) adjuvant/0.5 mL dose

[4] Adsorbed on aluminium hydroxide (0.5 mg Al^{3+})/0.5 mL dose

The other ingredients are: sodium chloride, sodium phosphate dibasic anhydrous, potassium phosphate mono anhydrous, potassium chloride, water for injections and recombinant human albumin (rHA) containing sodium, octanoate, and polysorbate 80.

What COVID-19 Vaccine Valneva looks like and contents of the pack
White to off-white suspension for injection (injection) in a glass multi-dose vial closed with rubber stopper and a flip-off plastic cap with aluminium seal.

Pack size: 10 multi-dose vials

Marketing Authorisation Holder
Valneva Austria GmbH
Campus Vienna Biocenter 3
1030 Vienna
Austria

Manufacturer

Valneva Scotland Limited
Oakbank Park Road
Livingston EH53 OTG
Scotland, UK

For any information about this medicine, please contact the Marketing Authorisation Holder by the following email-address:
covid19@valneva.com

This leaflet was last revised in April 2022.

This medicinal product has been authorised under a so-called 'conditional approval' scheme. This means that further evidence on this medicinal product is awaited. New information on this medicinal product will be reviewed at least every year and this leaflet will be updated as necessary.

Other sources of information
For more information scan or visit:
www.covid19-vaccine-valneva.com

The following information is intended for healthcare professionals only:

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.

Storage conditions

Store in a refrigerator at 2°C to 8°C.
Do not freeze.

Store vials in the original package in order to protect from light.

Shelf life

Unopened vial

12 months when stored in a refrigerator (2°C to 8°C).

After first opening

6 hours
Do not freeze.

Chemical and physical in-use stability of the vaccine has been demonstrated for 6 hours in the vial when stored at 2°C to 25°C. After this time, the vial must be discarded.

The COVID-19 Vaccine (inactivated, adjuvanted) Valneva does not contain any preservatives. Aseptic technique should be used to withdraw doses from the multi-dose vial. From a microbiological point of view, after first dose withdrawal the vaccine should be used as soon as practically possible and within 6 hours.

Handling and administration

The vaccine should be prepared and administered by a trained healthcare professional using aseptic techniques to ensure sterility of the suspension.

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of COVID-19 Vaccine Valneva.

- The vaccine comes ready to use.
- Unopened multi-dose vial should be stored at 2°C to 8°C.
- The vaccine may be stored between 2°C to 25°C when in use.
- Invert multiple times before use to form a uniform suspension. Do not shake
- The vaccine should be inspected visually for foreign particulate matter and discoloration prior to administration. Discard if discoloured or containing foreign particulate matter.
- COVID-19 Vaccine Valneva must not be mixed with other medicinal products or diluted in the same syringe.
- Use aseptic technique, cleanse vial stopper with a single-use antiseptic swab.
- Use a separate sterile administration needle and syringe for each individual.
- Use a low-dead volume syringe and/or needle combination, for which the combined dead volume is ≤ 30 µL, in order to extract 10 doses. The device should be compatible for intramuscular injection, with a needle of 21 gauge or narrower.
- If a syringe and needle combination is used, for which the combined dead volume is above 30 µL, less than ten doses can be extracted.
- Withdraw 0.5 mL of the vaccine.
- The preferred injection site is the muscle of the upper arm.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and any excess volume.
- **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.