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COVID-19 Vaccine (inactivated, adjuvanted) Valneva

COVID-19 vaccine (inactivated, adjuvanted, adsorbed)

What is COVID-19 Vaccine (inactivated, adjuvanted) Valneva and what is it used for?

COVID-19 Vaccine (inactivated, adjuvanted) Valneva is a vaccine for protecting people aged between 18 and 50 years against coronavirus disease 2019 (COVID-19). It is used for primary vaccination.

The vaccine contains whole particles of the original strain of SARS-CoV-2 (the virus that causes COVID-19) that has been inactivated (killed) and cannot cause the disease.

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

How is COVID-19 Vaccine (inactivated, adjuvanted) Valneva used?

COVID-19 Vaccine (inactivated, adjuvanted) Valneva is given as two injections, usually into the muscle of the upper arm, 4 weeks apart.

Arrangements for the supply of the vaccine will be the responsibility of national authorities. For more information about using COVID-19 Vaccine (inactivated, adjuvanted) Valneva, see the package leaflet or consult a healthcare professional.

How does COVID-19 Vaccine (inactivated, adjuvanted) Valneva work?

COVID-19 Vaccine (inactivated, adjuvanted) Valneva works by preparing the body to defend itself against infection with SARS-CoV-2. It contains the original strain of SARS-CoV-2 which has been inactivated and cannot cause the disease. The vaccine also contains two adjuvants (aluminium and cytosine phospho-guanine), substances that help strengthen the immune response to the vaccine.

When a person is given the vaccine, their immune system identifies the inactivated virus as foreign and makes antibodies and T cells against it. If, later, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the virus and be ready to defend against 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.

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What benefits of COVID-19 Vaccine (inactivated, adjuvanted) Valneva have been shown in studies?

The main study known as an immunobridging study compared the immune response induced by COVID-19 Vaccine (inactivated, adjuvanted) Valneva with that induced by the authorised COVID-19 vaccine Vaxzevria.

Results from the study, which involved nearly 3,000 people aged 30 years and older, showed that COVID-19 Vaccine (inactivated, adjuvanted) Valneva triggered the production of higher levels of antibodies against the original strain of SARS-CoV-2 than the comparator, Vaxzevria. In addition, the proportion of people who produced a high level of antibodies was similar for both vaccines. Additional data from this study also showed that the vaccine is as effective at triggering the production of antibodies in people aged between 18 and 29 as it is in people aged 30 years and older.

Based on the data provided, it was not possible to draw any conclusion on the immunogenicity of Valneva's vaccine (its ability to trigger the production of antibodies) in people above 50 years of age.

There were limited data on the immunogenicity of COVID-19 Vaccine (inactivated, adjuvanted) Valneva against variants of concern, including Omicron subvariants which were the dominant strains in many EU countries at the time of authorisation.

Can children be vaccinated with COVID-19 Vaccine (inactivated, adjuvanted) Valneva?

COVID-19 Vaccine (inactivated, adjuvanted) Valneva is not currently authorised for use in people below 18 years of age. EMA has agreed with the company on a plan to trial the vaccine in children at a later stage.

Can immunocompromised people be vaccinated with COVID-19 Vaccine (inactivated, adjuvanted) Valneva?

There are no data on 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 COVID-19 Vaccine (inactivated, adjuvanted) Valneva?

Animal studies do not show any harmful effects in pregnancy; however, data on the use of COVID-19 Vaccine (inactivated, adjuvanted) Valneva during pregnancy are limited.

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.

It is currently not known if the vaccine is present in human milk. Breastfeeding women should consult their healthcare professional before being vaccinated.

Can people with allergies be vaccinated with COVID-19 Vaccine (inactivated, adjuvanted) Valneva?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet must not receive the vaccine. People who are allergic to yeast-derived

components must also not receive the vaccine, as yeast is used to produce one of the ingredients of the vaccine.

Cases of anaphylaxis (severe allergic reaction) have occurred in people receiving COVID-19 vaccines. Therefore, as for all vaccines, COVID-19 Vaccine (inactivated, adjuvanted) Valneva should be given under close medical supervision, with the appropriate medical treatment available. People who have a severe allergic reaction when they are given the first dose of COVID-19 Vaccine (inactivated, adjuvanted) Valneva should not receive the second dose.

How well does COVID-19 Vaccine (inactivated, adjuvanted) Valneva work for people of different ethnicities and genders?

The immune response triggered by the vaccine in the main study was maintained across genders.

Participants in the main study were mainly of European descent; however there is no reason to suggest that the immune response induced by COVID-19 Vaccine (inactivated, adjuvanted) Valneva will vary across ethnicities.

What are the risks associated with COVID-19 Vaccine (inactivated, adjuvanted) Valneva?

The most common side effects with COVID-19 Vaccine (inactivated, adjuvanted) Valneva are mild and get better within a few days after vaccination. These include headache, muscle pain, tenderness and pain at the injection site, tiredness and nausea (feeling sick) or vomiting. These may affect more than 1 in 10 people.

Itching, hardening, swelling and reddening of the skin at the injection site, oropharyngeal (mouth and throat) pain and fever may occur in less than 1 in 10 people.

Lymphadenopathy (enlarged lymph nodes), dizziness, paraesthesia (sensations like numbness, tingling, pins and needles), dysgeusia (taste disturbance), syncope (fainting), hypoaesthesia (reduced sensation to touch, pain and temperature), migraine, diarrhoea, abdominal (belly) pain, hyperhidrosis (excessive sweating), rash, pain in the extremities, muscle spasms, joint pain and blood tests showing increases in red blood cell sedimentation rate (which may indicate an inflammation) are uncommon side effects (affecting less than 1 in 100 people).

Thrombocytopenia (low levels of blood platelets), photophobia (abnormal sensitivity of the eyes to light), urticaria (itchy rash) and thrombophlebitis (inflammation in a vein leading to a blood clot) are rare side effects (affecting less than 1 in 1,000 people).

Why is COVID-19 Vaccine (inactivated, adjuvanted) Valneva authorised in the EU?

Based on data comparing the immune response triggered by COVID-19 Vaccine (inactivated, adjuvanted) Valneva with that induced by an authorised COVID-19 vaccine, EMA concluded that COVID-19 Vaccine (inactivated, adjuvanted) Valneva is expected to be at least as effective as the comparator at protecting against the disease in people aged between 18 and 50 years.

Based on the data provided, it was not possible, however, to draw any conclusion on the vaccine's immunogenicity in people above 50 years of age; therefore, the vaccine is currently recommended only for use in people between 18 and 50 years of age. Regarding safety, the most common side effects with COVID-19 Vaccine (inactivated, adjuvanted) Valneva are mild and get better within a few days after vaccination.

EMA therefore decided that COVID-19 Vaccine (inactivated, adjuvanted) Valneva's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of COVID-19 Vaccine (inactivated, adjuvanted) Valneva?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of COVID-19 Vaccine (inactivated, adjuvanted) Valneva have been included in the summary of product characteristics and the package leaflet.

A risk management plan (RMP) for COVID-19 Vaccine (inactivated, adjuvanted) Valneva 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. A summary of the RMP is available.

Safety measures will be implemented for COVID-19 Vaccine (inactivated, adjuvanted) Valneva 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 the vaccine will provide monthly safety reports. In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will also give more information on the vaccine's long-term safety and benefits in the general population.

As for all medicines, data on the use of COVID-19 Vaccine (inactivated, adjuvanted) Valneva are continuously monitored. Suspected side effects reported with COVID-19 Vaccine (inactivated, adjuvanted) Valneva are carefully evaluated and any necessary action taken to protect patients.

Other information about COVID-19 Vaccine (inactivated, adjuvanted) Valneva

COVID-19 Vaccine (inactivated, adjuvanted) Valneva was recommended by EMA's human medicines committee (CHMP) on 23 June 2022 for a standard 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.