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Ervebo (*Ebola Zaire Vaccine* [*rVSVΔG-ZEBOV-GP, live*])

An overview of Ervebo and why it is authorised in the EU

What is Ervebo and what is it used for?

Ervebo is a vaccine to protect adults and children aged 1 year and older against Ebola virus disease caused by the Zaire Ebola virus.

Ervebo contains a virus known as vesicular stomatitis virus which has been weakened and modified to contain a protein from the Zaire Ebola virus. The vesicular stomatitis virus itself has little or no effect on humans. The vaccine only contains one protein from the Zaire Ebola virus and cannot cause Ebola virus disease.

How is Ervebo used?

Ervebo can only be obtained with a prescription and should be used in accordance with official recommendations issued at national level by public health bodies.

Ervebo is given by a trained healthcare worker. It is given as a single injection into the muscle around the shoulder (the deltoid) or a muscle of the thigh. Ervebo should be used in individuals at risk of infection with Zaire Ebola virus. People vaccinated with Ervebo should continue to take precautions to protect themselves from Ebola virus disease.

Healthcare workers and other carers who have been vaccinated with Ervebo should continue to apply standard precautions and extra infection control measures. They should continue to wear personal protective equipment when caring for patients with known or suspected Ebola virus disease to prevent contact with the patient's blood and body fluids and contaminated surfaces or materials such as clothing and bedding.

For more information about using Ervebo, see the package leaflet or contact your doctor or pharmacist.

How does Ervebo work?

The active substance in Ervebo contains a protein found on the Zaire Ebola virus. When a person receives the vaccine, it triggers an immune response against this viral protein. Later, if the person comes into contact with the actual virus, the immune system will recognise the viral protein and is already prepared to attack the virus and so protects the person from Ebola virus disease.

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What benefits of Ervebo have been shown in studies?

A main study showed that Ervebo was effective in preventing Ebola virus disease in adults at risk of infection during an outbreak. The study was conducted in Guinea during an Ebola outbreak and involved people who were either direct contacts or contacts of contacts of someone who had Ebola virus disease.

People received a single dose of Ervebo either immediately or after 21 days. The effectiveness of the vaccine to protect against confirmed Ebola virus disease was measured by comparing the number of cases occurring 10 to 31 days after vaccination in the group of people vaccinated immediately, versus the number of cases in the group of people who were vaccinated later. Amongst the 2,108 people who received immediate vaccination, none had Ebola virus disease between 10 days and 31 days after vaccination; amongst those whose vaccination was delayed (1429 people), 10 developed the disease within 31 days after vaccination.

The benefits of Ervebo in children were investigated in a second study which evaluated the immune response triggered by the vaccine by measuring the level of antibodies against the Zaire Ebola viral protein contained in Ervebo. Results showed that within 28 days of vaccination the level of antibodies in almost 500 children vaccinated with Ervebo was on average 18 times higher compared to that in about 170 children who received a dummy injection. This immune response was maintained 12 months after vaccination. Data also showed that the immune response to Ervebo in about 500 children was comparable to that observed in a group of almost 520 adults who received the vaccine.

What are the risks associated with Ervebo?

For the full list of side effects and restrictions of Ervebo, see the package leaflet. In general, the most common side effects with Ervebo occur within 7 days after vaccination and are mild to moderate in intensity.

The most common side effects with Ervebo in adults include pain, swelling and redness at the injection site, headache, pyrexia (fever), myalgia (muscle pain), fatigue (tiredness), arthralgia (joint pain), chills, decreased appetite and abdominal (belly) pain. They may affect more than 1 in 10 adults. Nausea (feeling sick), arthritis (pain and inflammation in the joints), skin rash, hyperhidrosis (excessive sweating) and mouth ulceration may affect up to 1 in 10 adults. In general, these side effects get better within 7 days.

The most common side effects with Ervebo in children include pain at the injection site, fever, headache, fatigue, decreased appetite, myalgia. They may affect more than 1 in 10 children. Dizziness, crying, mouth ulcers and swelling and itching at the injection site may affect up to 1 in 10 children.

Ervebo must not be used in people who are hypersensitive (allergic) to rice or to any ingredients of the vaccine.

Why is Ervebo authorised in the EU?

Ervebo is effective in protecting adults from Ebola virus disease; however, the duration of this protection is currently unknown.

Although the level and duration of protection of Ervebo against Ebola virus disease in children have not yet been determined, Ervebo generates an immune response in children which is comparable to adults, and the vaccine is therefore assumed to also protect children against the Ebola virus disease. Side effects with Ervebo were similar to those of most vaccines; they were mild to moderate in intensity and

generally lasted less than a week. The side effects observed in children are similar to those seen in adults.

The European Medicines Agency therefore decided that Ervebo's benefits are greater than its risks and that it can be authorised for use in the EU.

Ervebo was originally given 'conditional authorisation' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full authorisation.

What measures are being taken to ensure the safe and effective use of Ervebo?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ervebo have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ervebo are continuously monitored. Side effects reported with Ervebo are carefully evaluated and any necessary action taken to protect patients.

Other information about Ervebo

Ervebo received a conditional marketing authorisation valid throughout the EU on 11 November 2019. This was switched to a full marketing authorisation on 14 January 2021.

Further information on Ervebo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Ervebo.

This overview was last updated in 08-2023.