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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 aged 18 years 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 Zaire Ebola virus and cannot cause the disease.

How is Ervebo used?

Ervebo is given by a trained healthcare worker. It is given as a single 1 ml 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 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 also continue to apply standard precautions for safe injection and hygiene and wear personal protective equipment when caring for patients with known or suspected Ebola virus disease.

Ervebo can only be obtained with a prescription and should be used in accordance with official recommendations. 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 Ebola Zaire virus. When a person receives the vaccine, it triggers an immune response against the virus protein. Later, when the person comes into contact with the actual virus, the immune system recognises the virus 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.

What are the risks associated with Ervebo?

The most common side effects with Ervebo (which may affect more than 1 in 10 people) are pain, swelling and redness at the injection site, headache, fever, muscle pain, tiredness and joint pain. In general, these reactions occur within 7 days after vaccination, were mild to moderate in intensity and resolved in less than a week.

Ervebo must not be used in people who are hypersensitive (allergic) to rice or to any ingredients of the vaccines. For the full list of side effects and restrictions of Ervebo, see the package leaflet.

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. 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 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 12-2020.