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Mvabea (*MVA-BN-Filo, recombinant*)

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

What is Mvabea and what is it used for?

Mvabea is a vaccine to protect adults and children aged one year and older against Ebola virus disease caused by *Zaire ebolavirus*. It is used with another Ebola vaccine called Zabdeno as part of a vaccine regimen.

Mvabea contains a virus known as Vaccinia Ankara Bavarian Nordic which has been modified to produce 4 proteins from *Zaire ebolavirus* and three other viruses of the same group (*filoviridae*). The modified vaccinia Ankara Bavarian Nordic virus itself has no effect on humans. Mvabea only contains parts of the viruses and cannot cause Ebola virus disease.

How is Mvabea used?

Mvabea can only be obtained with a prescription and is given by a trained healthcare worker. It is given as a single injection about 8 weeks after an injection of Zabdeno. People who are at imminent risk of infection with Ebola virus and have received the Zabdeno and Mvabea injections more than 4 months earlier can receive a booster dose of Zabdeno.

Injections are given into the muscle around the shoulder (the deltoid) or a muscle of the thigh.

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

How does Mvabea work?

The active substance in Mvabea, when injected in the body, produces 4 viral proteins characteristic of *filoviridae*, the group of viruses that includes *Zaire ebolavirus*. When a person receives the vaccine regimen, the viral proteins trigger an immune response. If later on the person comes into contact with *Zaire ebolavirus*, the immune system recognises the viral proteins and is prepared to attack the virus, so protecting the person from the disease caused by Ebola virus.

What benefits of Mvabea have been shown in studies?

Five main studies showed that Mvabea, when used with Zabdeno, can trigger the production of antibodies capable of providing protection against *Zaire ebolavirus*. The studies involved a total of

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3,585 adults and children. Based on animal studies with a fully lethal dose of the virus, the antibody level generated in humans following vaccination with Zabdeno and Mvabea would be expected to lead to around 53% survival if infected with a fully lethal dose. However, the method used in the animal studies results in more severe infection than natural infection in humans. Although the vaccine regimen can provide protection against Ebola virus disease, the level and duration of protection are not yet known and the company will provide further data.

What are the risks associated with Mvabea?

The most common side effects in adults with Mvabea (which may affect more than 1 in 10 people) are pain, warmth and swelling at the injection site, tiredness, muscle pain and joint pain.

In children and adolescents aged 1 to 17 years, the most common side effects (which may affect more than 1 in 10 people) are pain at the injection site and tiredness.

For the full list of side effects and restrictions of Mvabea, see the package leaflet.

Why is Mvabea authorised in the EU?

Mvabea, used with Zabdeno as part of a 2-dose vaccine regimen, triggers an immune response that can provide protection against Ebola virus disease. Although the level and duration of protection against the virus have not yet been determined, the European Medicines Agency considered that the vaccine's benefits could be of great importance to help control an outbreak and prevent death. Regarding safety, most side effects are mild to moderate in severity and of short duration. The Agency therefore decided that Mvabea's benefits are greater than its risks and it can be authorised for use in the EU.

Mvabea has been authorised under 'exceptional circumstances'. This is because it has not been possible to obtain complete information about Mvabea for scientific and ethical reasons. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Mvabea?

Since Mvabea has been authorised under exceptional circumstances, the company that markets Mvabea will provide an update on the collection of data on the effectiveness of the vaccine regimen in the intended population on a yearly basis.

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

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

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

Other information about Mvabea

Mvabea received a marketing authorisation under exceptional circumstances valid throughout the EU on 01 July 2020.

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

This overview was last updated in 07-2020.