swissmedic

Summary report on authorisation dated 7 February 2025

Ervebo® (active substance: Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP, live))

Indication extension in Switzerland: 29 July 2024

Solution for injection for active immunisation (vaccination) of people aged 1 year and over to protect against Ebola virus disease (EVD) caused by the Zaire Ebola virus.

About the medicinal product

Ervebo contains the active substance Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP, live).

Ervebo is a vaccine to prevent Ebola virus disease (EVD) caused by the Zaire Ebola virus. The Ervebo vaccine was authorised by Swissmedic on 10 November 2021 to protect people aged 18 years and over.

The indication extension means that the Ervebo vaccine can now also be used to prevent EVD caused by the Zaire Ebola virus to protect people aged 1 year and over.

Ervebo should be used in accordance with the official vaccination recommendations.

Ervebo contains a live, attenuated virus, called the vesicular stomatitis virus. This virus contains an Ebola virus protein, and thereby triggers an immune response in the body.

EVD is a serious, often fatal disease. Ebola virus disease mainly occurs in Central and Western Africa. The vaccine is an important preventive measure for people with a high risk of infection.

The indication extension for Ervebo has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Ervebo in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; Procedure No. H/C/004554/II/0025, Reference

No. EMA/372877/2023) and has only conducted a limited scientific review.

Since the assessment of the clinical data was based on the assessment report of a foreign partner authority, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Summary report on authorisation are not fully met. Swissmedic refers to the authorisation of the foreign comparator product.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ervebo®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.