swissmedic

Summary report on authorisation dated 15 November 2024

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

Authorisation in Switzerland: 10 November 2021

Solution for injection for active immunisation (vaccination) of people aged 18 and over to protect against Ebola virus disease (EVD) caused by the Zaire Ebola virus.

## Information on authorisation

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 vaccine is authorised for people aged 18 and over.
The vaccine contains a live, attenuated virus called vesicular stomatitis virus which contains a protein from the Ebola virus and thus triggers an immune response in the body.

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

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; reference number EMEA/H/C/004554/0000) and has only conducted a limited scientific review.

## 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.