# Swiss Summary of the Risk Management Plan (RMP)

**for**

# Ervebo®

## Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)
## Solution for Injection

**Version 2.0 (September 2024)**
**based on EU-RMP V2.0**

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Ervebo® is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the "Arzneimittelinformation /Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Ervebo® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

MSD Merck Sharp and Dohme AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Ervebo®.

**Summary of risk management plan for ERVEBO**

This is a summary of the risk management plan (RMP) for ERVEBO. The RMP details important risks of ERVEBO, how these risks can be minimised, and how more information will be obtained about ERVEBO's risks and uncertainties (missing information).

ERVEBO's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ERVEBO should be used.

This summary of the RMP for ERVEBO should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of ERVEBO's RMP.

## I. The Medicine and What it is Used for

ERVEBO is indicated for active immunization of individuals 1 year of age or older to protect against Ebola Virus Disease (EVD) caused by Zaire Ebola virus. The use of Ervebo should be in accordance with official vaccination recommendations (see product labeling for the full indication). It contains rVSVΔG-ZEBOV-GP as the active substance and it is given by intramuscular administration.

Further information about the evaluation of ERVEBO's benefits can be found in ERVEBO's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: link to product's EPAR summary landing page on the EMA webpage.

## II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of ERVEBO, together with measures to minimise such risks and the proposed studies for learning more about ERVEBO's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;

- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.
- Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of ERVEBO is not yet available, it is listed under 'missing information' below.

## II.A List of Important Risks and Missing Information

Important risks of ERVEBO are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of ERVEBO. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

### Table II.A.1: List of Important Risks and Missing Information

| **List of Important Risks and Missing Information** | |
|---|---|
| Important identified risks | None |
| Important potential risks | • Viral shedding/secondary transmission to close contacts, particularly immunocompromised hosts |
| Missing information | • Exposure during pregnancy<br>• Exposure during lactation<br>• Exposure in HIV-infected individuals |

## II.B Summary of Important Risks

### Table II.B.1: Viral Shedding/Secondary Transmission to Close Contacts, Particularly Immunocompromised Hosts

| | |
|---|---|
| Evidence for linking the risk to the medicine | Literature |
| Risk factors and risk groups | Vaccine recipients should attempt to avoid close association with and exposure of high-risk individuals to blood and bodily fluids for up to 6 weeks following vaccination. People who develop vesicular rash after receiving the vaccine should cover the vesicles until they heal.<br>High-risk individuals include:<br>• Immunocompromised individuals and individuals receiving immunosuppressive therapy<br>• Pregnant or breast-feeding women<br>• Children <1 year of age<br>Individuals administered rVSVΔG-ZEBOV-GP should not donate blood for at least 6 weeks postvaccination. |
| Risk minimisation measures | Routine risk minimisation measures:<br>Special warnings and precautions for use section of the product information.<br>*What you need to know before you receive ERVEBO* section of the patient information. |

## Table II.B.1: Viral Shedding/Secondary Transmission to Close Contacts, Particularly Immunocompromised Hosts

| | |
|---|---|
| Additional pharmacovigilance activities | Additional pharmacovigilance activities:<br>Viral shedding:<br>V920-015 African-Canadian Study of HIV-Infected Adults and a Vaccine for Ebola (ACHIV-Ebola) |

## Table II.B.2: Exposure During Pregnancy

| | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Special warnings and precautions for use and the Fertility, pregnancy and lactation sections of the product information.<br>*What you need to know before you receive ERVEBO* section of the patient information. |
| Additional pharmacovigilance activities | Additional pharmacovigilance activities:<br>WHO-sponsored trial (V920-EAP5): Compassionate ring vaccination study to evaluate the safety of the Ebola vaccine in the Democratic Republic of the Congo |

## Table II.B.3: Exposure During Lactation

| | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Special warnings and precautions for use and the Fertility, pregnancy and lactation sections of the product information.<br>*What you need to know before you receive ERVEBO* section of the patient information. |
| Additional pharmacovigilance activities | Additional pharmacovigilance activities:<br>WHO-sponsored trial (V920-EAP5): Compassionate ring vaccination study to evaluate the safety of the Ebola vaccine in the Democratic Republic of the Congo |

**Table II.B.4: Exposure in HIV-Infected Individuals**

| | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Special warnings and precautions for use section of the product information.<br>*What you need to know before you receive ERVEBO* section of the patient information. |
| Additional pharmacovigilance activities | Additional pharmacovigilance activities:<br>V920-015 African-Canadian Study of HIV-Infected Adults and a Vaccine for Ebola (ACHIV-Ebola) |

## II.C Post-Authorisation Development Plan

### II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of ERVEBO.

### II.C.2 Other Studies in Post-Authorisation Development Plan

V920-015 African-Canadian Study of HIV-Infected Adults and a Vaccine for Ebola (ACHIV-Ebola)

Rationale: Future Ebola outbreaks are likely to occur in countries where HIV infection is endemic or present in large segments of the population. It is important to know whether V920 will be safe and effective in this patient population as efforts to roll out vaccination during an epidemic need to be quick and HIV testing may not be possible. Twenty-two known HIV-infected individuals have received V920 in the Phase 2 placebo-controlled trial in Liberia (V920-009), and the preliminary safety profile in this small number of subjects appeared to be generally similar to the overall vaccinated population. However, safety and immunogenicity of V920 has not been formally evaluated in HIV-infected individuals in a randomized controlled manner to date. This is what is intended with this study.

Primary Objectives:

1) Evaluate the safety and tolerability of V920 in HIV-infected adults and adolescents.

2) Evaluate the immunogenicity of V920 via ZEBOV- specific antibody responses induced by V920 in HIV-infected adults and adolescents.

V920 Expanded Access Protocol #5 (V920-EAP5) in the Democratic Republic of Congo (Amendment #1)

Rationale: The results of the V920 vaccination have been very encouraging. However, because the vaccine was not approved at the time of the outbreak, the national epidemic response coordinator and their team in the DRC have deemed it necessary to implement ring vaccination in order to control the surge of EVD to control the spread of the disease.

Primary Objectives:

1) To evaluate the safety of the V920 vaccine by following SAEs for 21 days for all participants.

Secondary Objectives:

1) To summarize the cumulative incidence of EVD laboratory-confirmed cases amongst eligible persons after 21 days of monitoring, where a ring vaccination or geographically targeted vaccination strategy has been used.

2) To document the safety of a single dose of V920 vaccine in evaluating the solicited AEs (fever, headaches, tiredness, diarrhea, vomiting, myalgia, arthralgia and local reactogenicity) for 21 days and the unsolicited AEs during the 21 days of follow-up for all participants.