Swiss Summary of the Risk Management Plan (RMP)

for

ENFLONSIA®

Active Substance: Clesrovimab

RMP summary version 1.0 (March 2026)

Based on EU-RMP Version 1.0 (11-Sep-2025)

Marketing Authorisation Holder: MSD Merck Sharp & Dohme AG, Lucerne

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 ENFLONSIA 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 ENFLONSIA 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 ENFLONSIA.

Summary of risk management plan for ENFLONSIA (clesrovimab)

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

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

This summary of the RMP for ENFLONSIA 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 ENFLONSIA's RMP.

I. The Medicine and What it is Used for

ENFLONSIA is indicated for the prophylaxis of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants born before or during their first RSV season. ENFLONSIA should be used in accordance with official recommendations. It contains clesrovimab as the active substance and it is given by intramuscular injection.

Further information about the evaluation of ENFLONSIA's benefits can be found in ENFLONSIA's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/enflonsia.

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

Important risks of ENFLONSIA, together with measures to minimise such risks and the proposed studies for learning more about ENFLONSIA'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 caregivers of infants 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.*

II.A List of Important Risks and Missing Information

Important risks of ENFLONSIA 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 ENFLONSIA. 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	None
Missing information	None

II.B Summary of Important Risks and Missing Information

There are no important identified risks, important potential risks or missing information for ENFLONSIA.

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 ENFLONSIA.

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

There are no studies required for ENFLONSIA.