

RISK MANAGEMENT PLAN FOR REZZAYO®

Based on EU RMP version 1.1, dated 10 July 2026

Product name	REZZAYO® 200 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Active substance	Rezafungin acetate
Marketing Authorisation Holder	Mundipharma Medical Company, Hamilton/Bermuda, Zweigniederlassung Basel

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 REZZAYO® 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 / Informazioni sul medicinale" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorisation.

Please note that the reference document which is valid and relevant for the effective and safe use of REZZAYO® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament / Informazioni sul medicinale" (see www.swissmedic.ch) approved and authorised by Swissmedic. Mundipharma Medical Company is fully responsible for the accuracy and correctness of the content of the published RMP summary of REZZAYO®.

Summary of RMP for REZZAYO (Rezafungin)

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

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

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

I. The Medicine and What it is Used For

REZZAYO is indicated for invasive candidiasis or for prevention of Candida infections following bone marrow transplant in adults and it is given by intravenous route only.

Further information about the evaluation of REZZAYO's benefits can be found in REZZAYO's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage [Rezzayo | European Medicines Agency \(EMA\)](#).

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

Important risks of REZZAYO, together with measures to minimise such risks and the proposed studies for learning about REZZAYO'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, including PSUR assessment, 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 REZZAYO 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 REZZAYO. 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

Not applicable.

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 REZZAYO.

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

There are no studies required for REZZAYO.