CSL Behring

Respreeza

Human Alpha1-Proteinase Inhibitor A1-PI

Swiss Summary of Risk Management Plan

Version number of RMP: 4.0

Marketing Authorization Holder: CSL Behring AG

Date: 13-Oct-2020

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 minimize them.
The RMP summary of Respreeza 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 Respreeza in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. CSL Behring AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Respreeza.

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The medicine and what it is used for

Respreeza is authorized for maintenance treatment, to slow the progression of emphysema in adults with documented severe A1-PI deficiency (see SmPC ("Arzneimittelinformation/ Information sur le médicament) for the full indication). It contains Human Alpha1-Proteinase Inhibitor A1-PI as the active substance and it is given by infusion.

Risks associated with the medicine and activities to minimize or further characterize the risks

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

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

- Specific information, such as warnings, precautions, and advice on correct use, in the SmPC ("Arzneimittelinformation/ Information sur le médicament") addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including PSUR assessment 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 Respreeza is not yet available, it is listed under 'missing information' below.

List of important risks and missing information

Important risks of Respreeza are risks that need special risk management activities to further investigate or minimize 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 Respreeza. 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).

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• Transmission of infectious agents
Missing information	• Use in pregnancy/lactation • Use in patients with hepatic impairment

Summary of important risks

Important potential risk: Transmission of Infectious Agents	
Evidence for linking the risk to the medicine	Clinical study safety data. Postmarketing data obtained from CSLB Global Safety Database in February 2020.
Risk factors and risk groups	The risk is increased with exposure to other blood products. It is also increased in iv drug abusers, homosexuals engaged in high-risk sexual behavior, health care professionals, and others.
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.4 Additional risk minimization measures: None

Missing information: Use in pregnancy/lactation	
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.6 Additional risk minimization measures: None

Missing information: Use in patients with hepatic impairment	
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.2 Additional risk minimization measures: None

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Post-authorization development plan

Studies which are conditions of the marketing authorization

As per an obligation to complete a post-authorization efficacy study, CSLB is committed to conducting and submitting the results of a randomized, long-term, efficacy study (by 31 March 2025). Further updates will be provided upon protocol agreement with the competent Health Authorities.

Other studies in post-authorization development plan

There are no studies required for Respreeza.

Summary of changes to the Swiss RMP Summary over time

Version	Date	Change	Comment
01	24-Oct-2016	Initial document	Initial document, based on EU RMP Version 3.1, 20-Oct-2016
02	13-Oct-2020	1. Important risk 'Anaphylactic reactions and Hypersensitivity' removed. 2. Potential risks 'Increased or unknown risks with home based self-administration' and 'Medication errors' removed. 3. Missing information 'Limited experience in the geriatric population', 'No experience in patients who have undergone lung transplantation or volume reduction surgery' and 'Limited experience in patients with FEV1<35%' removed.	Version based on EU Risk Management Plan Version 4.0; 19-Jun-2020 Required changes due to usage of new EU-RMP template as per GVP Module V Rev. 2.