GLASSIA®

Alpha$_1$-Proteinase Inhibitor (Human)

SWISS SUMMARY OF RISK MANAGEMENT PLAN

Version number of RMP: 5.0

Marketing Authorization Holder: Ideogen AG

Date: 30 Jan 2024

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 risk as well as to prevent or minimize them.

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

Summary of risk management plan for Glassia® [Alpha$_1$-Proteinase Inhibitor (Human)]:

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

Glassia® Summary of Product Characteristics (SmPC)/ Product information (PI) and its package leaflet give essential information to healthcare professionals on how Glassia® should be used.

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

I. The medicine and what it is used for

Glassia® is authorised for:

The chronic substitution therapy required due to a severe hereditary deficiency of Alpha$_1$-Proteinase Inhibitor with clinically evident emphysema in adults with proteinase inhibitor genotype/phenotype (Z, Z), (Z, null), (null, null), (S, Z), (Mmalton, Z), or (PLowell, Z).

II. Risks associated with the medicine and activities to minimise or further characterise the risks

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

Measures to minimize the risks identified for medicinal are: specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC/PI addressed to healthcare professionals. Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed. These measures constitute routine pharmacovigilance activities.

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

II.A List of important risks and missing information

Important risks of Glassia® 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 Glassia®. 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.

List of important risks and missing information	
Important identified risk	• Hypersensitivity
Important potential risk	• Transmission of infectious agents
Missing information	• Long term safety • Long term Immunogenicity • Exposure during pregnancy • Use in Breastfeeding • Pediatric Use • Geriatric Use • Limited experience in patients who have undergone lung transplantation or volume reduction surgery • Limited experience in patients with forced expiratory volume in 1 second (FEV1) <35% • Use in patients with hepatic impairment

II.B Summary of important risks

Identified Risk of Severe Hypersensitivity Reactions	
Evidence for linking the risk to the medicine	Glassia® may contain trace amounts of IgA. Patients with known antibodies to IgA, which can be present in patients with selective or severe IgA deficiency, have a greater risk of developing severe hypersensitivity and anaphylactic reactions.
Risk factors and risk groups	1. Patients with selective IgA deficiencies who have antibodies against IgA since the 1st administration. 2. Patients hypersensitive to Glassia® or any of its components.
Risk minimizations measures	Routine risk communication and activities recommending specific clinical measures to address the risk: appear in SmPC/PI. Glassia® is contra-indicated in IgA deficient patients with antibodies against IgA and in individuals with a history of severe immediate hypersensitivity reactions, including anaphylaxis, to AAT products.
Potential Risk of Transmission of Infectious Agents	
Evidence for linking the risk to the medicine	Because this product is made from human blood, it may carry the risk of transmitting infectious agents, e.g. viruses such as parvovirus B19, hepatitis C or HIV, theoretically the Creutzfeldt-Jakob disease (CJD) agent or Creutzfeldt-Jakob Disease variant (vCJD) agents, unknown infectious agents.
Risk factors and risk groups	Any treated patient.
Risk minimization measures	Routine risk communication: addressed in the SmPC/PI.. The risk of transmitting an infectious agent has been minimized by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections and by inactivating and removing certain viruses during the manufacturing process.
Missing information of Long-term safety	
Evidence for linking the risk to the medicine	Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with AAT/ Glassia® are not available.
Risk minimization measures	Routine risk communication: addressed in the SmPC/PI.
Missing information of Immunogenicity	
Evidence for linking the risk to the medicine	As with all therapeutic proteins, there is a potential for immunogenicity.

Risk minimization measures	Routine risk communication: addressed in the SmPC/PI.
Missing information of exposure during pregnancy	
Evidence for linking the risk to the medicine	There is no data with Glassia® use in pregnant women to inform a drug-associated risk.
Risk minimization measures	Routine risk communication: addressed in the SmPC/PI.
Missing information of use in breastfeeding	
Evidence for linking the risk to the medicine	There is no information regarding the presence of Glassia® in human milk, the effect on the breastfed infant, or the effects on milk production.
Risk minimization measures	Routine risk communication: addressed in the SmPC/PI.
Missing information of pediatric use	
Evidence for linking the risk to the medicine	Safety and effectiveness in pediatric patients have not been established.
Risk minimization measures	Routine risk communication: addressed in the SmPC/PI.
Missing information of geriatric use	
Evidence for linking the risk to the medicine	Safety and effectiveness in patients over 65 years of age have not been established.
Risk minimization measures	Routine risk communication: addressed in the SmPC/PI.
Limited experience in patients who have undergone lung transplantation or volume reduction surgery	
Evidence for linking the risk to the medicine	Safety and effectiveness in patients who have undergone lung transplantation or volume reduction surgery have not been established.
Risk minimization measures	Routine risk communication: None
Limited experience in patients with forced expiratory volume in 1 second (FEV1) <35%	
Evidence for linking the risk to the medicine	Safety and effectiveness in patients with forced expiratory volume in 1 second (FEV1) <35% have not been established.
Risk minimization measures	Routine risk communication: None
Missing information: Use in patients with hepatic impairment	

Evidence for linking the risk to the medicine	Safety and effectiveness in patients with hepatic impairment have not been established.
Risk minimization measures	Routine risk communication: None

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

Not applicable.

II.C.2 Other studies in post-authorisation development plan

Not applicable.