Swiss Summary of the Risk Management Plan (RMP)

Serum autolog Insel, Augentropfen

(Human Blood Serum, Autologous Eye Drops)

Active substance(s): Human blood serum, autologous

Product(s) concerned: Serum autolog Insel, Augentropfen

Based on RMP Version 1.0

Data lock point: 26 November 2025

Marketing Authorisation Holder: Insel Gruppe AG, Bern

Disclaimer:

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 Serum autolog Insel, Augentropfen 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 Serum autolog Insel, Augentropfen in Switzerland is the «Arzneimittelinformation / Information sur le médicament» (see www.swissmedic.ch) approved and authorized by Swissmedic. Insel Gruppe AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Serum autolog Insel, Augentropfen.

Summary of Risk Management Plan for Serum autolog Insel, Augentropfen (human blood serum, autologous)

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

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

I. The Medicine and What it is Used For

Serum autolog Insel, Augentropfen is authorised for the treatment of dry eye disease (keratoconjunctivitis sicca) in patients aged 18 years and older who are not free of symptoms with another approved therapy (see SmPC for the full indication). It contains human blood serum, autologous as the active substance and it is given as eye drops for ocular use.

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

Important risks of Serum autolog Insel, Augentropfen, together with measures to minimise such risks and the proposed activities for learning more about the medicine'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 Periodic Safety Update Report (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 Serum autolog Insel, Augentropfen is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Serum autolog Insel, Augentropfen 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 Serum autolog Insel, Augentropfen. 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).

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

List of Important Risks and Missing Information	
Important identified risks	Transmission of infectious disease related to the procedure Contamination during use by the patient
Important potential risks	Iron deficiency (anaemia) related to the procedure Rare therapy-related complications
Missing information	Pregnant or breastfeeding women Paediatric population Patients using contact lenses Long-term efficacy

II.B Summary of Important Risks

Important Identified Risk: Transmission of infectious disease related to the procedure	
Evidence for linking the risk to the medicine	This is a risk based on the biological nature of the product. The evidence is weak but plausible.
Risk factors and risk groups	Patients receiving improperly screened or processed serum might be at a higher risk, but this is prevented by the adherence to the requirements for serology (see below).
Risk minimisation measures	Routine risk minimisation measures: SmPC sections: Warnhinweise und Vorsichtsmassnahmen; Kontraindikationen. Package leaflet section: Wann ist bei der Anwendung von Serum autolog Augentropfen Vorsicht geboten? and Wie verwenden Sie Serum autolog Insel, Augentropfen? Additional risk minimisation measures: None
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

Important Identified Risk: Contamination during use by the patient	
Evidence for linking the risk to the medicine	Improper handling by the patient may lead to contamination. The evidence is strong and supported by known risks of inadequate eye drop containers, but there is no evidence given in the literature whether a contamination during use with Novelia® bottles has occurred.
Risk factors and risk groups	Patients with limited dexterity and poor hygiene practices are at increased risk. Patients who store the product at home without proper refrigeration, and individuals with limited understanding of storage instructions, are also at higher risk.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections Dosierung/Anwendung.

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	Package leaflet sections: Wie verwenden Sie Serum autolog Insel, Augentropfen? Additional risk minimisation measures: None
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

Important Potential Risk: Iron deficiency (anaemia) related to the procedure	
Evidence for linking the risk to the medicine	This risk is based on clinical observations indicating that repeated blood draws for serum preparation may lead to iron depletion, particularly in patients with borderline iron levels. The evidence is considered moderate and clinically plausible.
Risk factors and risk groups	Patients with low baseline haemoglobin, frequent blood donations, menstruating women, and individuals with poor nutritional status are at higher risk.
Risk minimisation measures	Routine risk minimisation measures: SmPC section: Kontraindikationen. Additional risk minimisation measures: None
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

Important Potential Risk: Rare therapy-related complications	
Evidence for linking the risk to the medicine	Isolated case reports
Risk factors and risk groups	Patients with pre-existing ocular inflammation, autoimmune conditions, or hypersensitivity may be more susceptible to complications.
Risk minimisation measures	Routine risk minimisation measures: SmPC section: Unerwünschte Wirkungen. Package leaflet section: Welche Nebenwirkungen können Serum autolog Insel, Augentropfen haben? Additional risk minimisation measures: None
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

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Missing Information: Use in pregnant or breastfeeding women, paediatric patients, and patients using contact lenses	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections: Dosierung/Anwendung and Interaktionen and Schwangerschaft, Stillzeit. Package leaflet sections: Dürfen Serum autolog Augentropfen während einer Schwangerschaft oder in der Stillzeit angewendet werden? and Wie verwenden Sie Serum autolog Insel, Augentropfen? Additional risk minimisation measures: None
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

Missing Information: Long-term efficacy	
Risk minimisation measures	Routine risk minimisation measures: SmPC section: Dosierung/Anwendung Additional risk minimisation measures: None
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

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 Serum autolog Insel, Augentropfen.

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

A prospective patient registry is maintained as an additional pharmacovigilance activity. This registry collects data on all patients and their preparations for autologous serum eye drops. The registry is organised into annual collection periods and is standardised among all manufacturers in Switzerland for annual reporting to Swissmedic.

The registry collects data including:

- Patient demographics and consent documentation
- Prescribing institution
- Indication
- Manufacturing data (dates of blood collection, serum concentration)
- Treatment details (eyes treated, frequency of application, dilution medium)
- Annual Ocular Surface Disease Index (OSDI) assessment
- Annual patient subjective benefit assessment
- Adverse events according to the RMP, including whether a report to Swissmedic has been filed

This registry addresses all safety concerns identified in the RMP, including long-term efficacy monitoring.

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