Swiss Summary of the Risk Management Plan (RMP) Serum autolog USZ, Augentropfen

(Human Blood Serum, Autologous Eye Drops)

Active substance(s):	Serum humanum autologum
Product(s) concerned:	Serum autolog USZ, Augentropfen
Based on RMP:	Version 1.0
Data lock point:	27.11.2025
Marketing Authorisation Holder:	ZüriPharm AG, Schlieren

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 USZ, 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 USZ, Augentropfen in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. ZüriPharm AG, Schlieren is fully responsible for the accuracy and correctness of the content of the published summary RMP of serum autolog USZ, Augentropfen.

Summary of Risk Management Plan for Serum autolog USZ, Augentropfen (Human Blood Serum, Autologous Eye Drops)

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

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

I. The medicine and what it is used for

Serum autolog USZ, Augentropfen is authorized for dry eye disease (keratoconjunctivitis sicca) in patients aged 18 and older who are not free of symptoms with another approved therapy (see SmPC for the full indication). It contains “Serum humanum autologum” as the active substance and it is intended for ocular use.

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

Important risks of serum autolog USZ, Augentropfen, together with measures to minimize such risks and the proposed studies for learning more about serum autolog USZ, Augentropfen’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 package leaflet and SmPC 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 minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 USZ, 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 USZ, Augentropfen are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely topically 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 USZ, 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).

List of important risks and missing information	
Important identified risks	Transmission of infectious disease related to the procedure Contamination during use by patient
Important potential risks	Iron deficiency (Anemia) related to the procedure Rare therapy-related complications
Missing information	Pregnant or breastfeeding women Pediatric 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	No data available.
Risk minimisation measures	Routine risk communication: SmPC section: Warnhinweise und Vorsichtsmassnahmen and Kontraindikationen PL section: Wann dürfen Serum autolog USZ, Augentropfen nicht angewendet werden? Wann sind bei der Anwendung von Serum autolog USZ, Augentropfen Vorsicht geboten? Wie verwenden Sie Serum autolog USZ, Augentropfen?
Additional pharmacovigilance activities	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 patients can lead to contamination and is supported by the scientific literature which describes only one case of an eye infection during the treatment with ASED due to a contaminated ASED container.
Risk factors and risk groups	age-related physical difficulties, improper handling, poor (hand) hygiene. Patients who store ASED at home without proper refrigeration, and individuals with limited understanding of storage instructions are also at higher risk.
Risk minimisation measures	Routine risk communication: SmPC section: Dosierung / Anwendung and Warnhinweise und Vorsichtsmassnahmen PL section: Wie verwenden Sie Serum autolog USZ, Augentropfen? And Weitere Hinweise
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Data collection from participation in the severe dry eye disease registry.

Important potential risk: Iron deficiency (anemia)	
Evidence for linking the risk to the medicine	known medical side-effect of regular blood draws
Risk factors and risk groups	General risk factors for anemia are, eg, female of childbearing years, history of anemia, patients with pre-existing or concurrent bleeding, patient with malabsorption disorders (celiac disease, crohn's disease) that may impair iron absorption. Elderly having poor nutrition and/or chronic disease-causing blood loss or poor iron adsorption may also be at higher risk of developing an anaemia. These populations should be closely monitored.
Risk minimisation measures	Routine risk communication: SmPC section: Kontraindikationen PL section: Wann dürfen Serum autolog USZ, Augentropfen nicht angewendet werden?
Additional pharmacovigilance activities	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 communication: SmPC section: Warnhinweise und Vorsichtsmassnahmen and Unerwünschte Wirkungen and Interaktionen PL section: Welche Nebenwirkungen können Serum autolog USZ, Augentropfen haben?
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Data collection from participation in the severe dry eye disease registry.

Missing information: Use of autologous serum eye drops in pregnant or lactating women, paediatric patients, and patients using contact lenses	
Evidence for linking the risk to the medicine	There are no published studies on the safety of autologous serum eye drops during pregnancy or breastfeeding. However, blood donation during pregnancy is universally contraindicated due to significant maternal and foetal risks.
Risk factors and risk groups	Pregnant and lactating women, Pediatric patients under the age of 18 years as well as contact lens wearers. No waiver for pediatric children was requested by the applicant.
Risk minimisation measures	Routine risk communication: SmPC section: Kinder und Jugendliche and Interaktionen and Schwangerschaft, Stillzeit PL section: Dürfen Serum autolog USZ, Augentropfen während einer Schwangerschaft oder in der Stillzeit angewendet werden? and Was sollte dazu beachtet werden? and Wie verwenden Sie Serum autolog USZ, Augentropfen?

Missing information: Long-term efficacy	
Evidence for linking the risk to the medicine	Lack of large-scale controlled studies on long-term efficacy.
Risk factors and risk groups	All populations
Risk minimisation measures	Routine risk communication: SmPC section: Klinische Wirksamkeit

II.C Post-authorisation development plan

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

The following studies are conditions of the marketing authorisation:

As additional pharmacovigilance activity a registry is implemented. This prospective registry collects data on all patients and their preparations for serum eye drops intended for autologous use.

A prospective registry collects data on all patients and their preparations for serum eye drops intended for autologous use. The registry is organized into annual collection periods. It is standardized among all manufacturers in Switzerland and used for annual reporting to Swissmedic. The basic document is an Excel spreadsheet (see Appendix). The following data is recorded in the registry:

- Surname, first name and date of birth of the patient.
- Documentation of the mandatory declaration of consent for the further use of health-related personal data for research purposes.
- Prescribing institution, clinic or ophthalmologist.
- Indication: Diagnosis, an off-label use is indicated as such. Additional diagnoses are mentioned if possible.
- Date therapy started, with the date of the very first blood collection given as the date therapy started
- All manufacturing data for the reporting period are listed (the date of blood collection given as the date of manufacture, serum concentration and dilution medium used).
- Eyes treated, average frequency of application
- The Ocular Surface Disease Index (OSDI) is surveyed once a year, starting at baseline
  OSDI: Created by the Outcomes Research Group at Allergan Inc., the OSDI is a 12-item questionnaire designed to quickly assess symptoms of ocular irritation in dry eye disease, as well as their impact on vision-related functioning, over the past week. The questionnaire has three subscales: ocular symptoms, vision-related function, and environmental triggers. Patients rate their responses on a scale of 0 to 4, where 0 corresponds to 'none of the time' and 4 to 'all of the time'. A final score ranging from 0 to 100 is calculated, with scores of 0-12 indicating normal condition, 13-22 indicating mild condition, 23-32 indicating moderate condition and scores greater than 33 indicating severe condition. The OSDI can be accessed at https://www.reviewofoptometry.com/CMSDocuments/2022/05/OSDI.pdf, among other places.
- The patient's subjective benefit is assessed once a year compared to before therapy, starting only after the first production, measured on a scale from -10 (much worse) to +10 (much improved), with 0 indicating no change.
- Adverse events (AE) according to RMP are recorded, as well as whether a Swissmedic report has been filed.

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

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

There are no studies required for Serum autolog USZ, Augentropfen except the required mandatory PSUR.

Summary of changes to the Swiss RMP Summary over time

Version	Date	Safety concerns	Comment
1.0	27.11.2025	Initial document	Initial document