Swiss Summary of the Risk Management Plan (RMP)

Serum autolog LUKS, Augentropfen

(Human Blood Serum, Autologous Eye Drops)

Active substance(s): Human blood serum, autologous

Product(s) concerned: Serum autolog LUKS, Augentropfen

Based on RMP Version 1.0

Data lock point: 24 November 2025

Marketing Authorisation Holder: LUKS Spitalbetriebe AG, Lucerne

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

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

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

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

I. The Medicine and What it is Used For

Serum autolog LUKS, 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.

Dry eye disease is a condition in which the eye does not produce enough tears, or the tears evaporate too quickly, leaving the surface of the eye inadequately protected. Without adequate tear film, the eye surface can become damaged and inflamed, potentially leading to symptoms such as irritation, burning, blurred vision, and in severe cases, ulceration or infection.

Serum autolog LUKS, Augentropfen is prepared from the patient's own blood. The serum contains naturally occurring growth factors, vitamins, and proteins that closely resemble the composition of natural tears. These components support healing and maintenance of the eye surface, provide nutrients to promote cellular repair, and offer bactericidal properties that may reduce the risk of contamination or infection. The product is available in two concentrations: 100% and 50% serum, which may be diluted with balanced salt solution (BSS).

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

Important risks of Serum autolog LUKS, 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 LUKS, 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 LUKS, 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 LUKS, 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 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	
Evidence for linking the risk to the medicine	This is an identified risk. There is no evidence given in the literature whether a transmission due to the application by a third person had occurred.
Risk factors and risk groups	No data available.
Risk minimisation measures	Routine risk minimisation measures: SmPC section Warnhinweise und Vorsichtsmassnahmen PL section Wann ist bei der Anwendung von Serum autolog Augentropfen Vorsicht geboten? and Wie verwenden Sie Serum autolog Augentropfen? Additional risk minimization 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	This is an identified risk. There is no evidence given in the literature whether a contamination during use had occurred.
Risk factors and risk groups	No data available.

Risk minimisation measures	Routine risk minimisation measures: SmPC section Dosierung/Anwendung PL section Wie verwenden Sie Serum autolog Augentropfen? Additional risk minimization 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	Clinical observations indicating that repeated blood draws for serum preparations 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	Low baseline hemoglobin, frequent blood donations, menstruating women, poor nutritional status
Risk minimisation measures	Routine risk minimisation measures: Pre-donation screening Additional risk minimization 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	Presumably autoimmune conditions, hypersensitivity
Risk minimisation measures	Routine risk minimisation measures: Identifying patients with known conditions, sensitivities Additional risk minimization measures: None.
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

Missing Information: Use in pregnant or lactating women, paediatric patients, and patients using contact lenses	
Evidence for linking the risk to the medicine	No data available.

Risk factors and risk groups	No data available.
Risk minimisation measures	Routine risk minimisation measures: SmPC section Dosierung/Anwendung and Interaktionen and Schwangerschaft, Stillzeit PL section Wann ist bei der Anwendung von Serum autolog Augentropfen Vorsicht geboten? und Dürfen Serum autolog Augentropfen während einer Schwangerschaft oder in der Stillzeit angewendet werden? und Wie verwenden Sie Serum autolog Augentropfen? Additional risk minimization measures: None.
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

Missing Information: Long-term efficacy	
Evidence for linking the risk to the medicine	Lack of large-scale controlled studies.
Risk factors and risk groups	No data available.
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

Not applicable

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

Not applicable