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Swiss Summary of the Risk Management Plan (RMP)

Sérum autologue ICH, collyre

(Human Blood Serum, Autologous Eye Drops)

Active substance(s): Human blood serum, autologous

Product(s) concerned: Sérum autologue ICH, collyre

Based on RMP Version 1.0

Data lock point: 24 November 2025

Marketing Authorisation Holder: Hôpital du Valais, Institut Central des Hôpitaux (ICH), Sion

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 Sérum autologue ICH, collyre 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 Sérum autologue ICH, collyre in Switzerland is the «Arzneimittelinformation / Information sur le médicament» (see www.swissmedic.ch) approved and authorized by Swissmedic. Institut Central des Hôpitaux is fully responsible for the accuracy and correctness of the content of the published summary RMP of Sérum autologue ICH, collyre.

Summary of Risk Management Plan for Sérum autologue ICH, collyre (human blood serum, autologous)

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

Sérum autologue ICH, collyre's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sérum autologue ICH, collyre should be used.

This summary of the RMP for Sérum autologue ICH, collyre should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary.
Important new concerns or changes to the current ones will be included in updates of Sérum autologue ICH, collyre's RMP.

I. The Medicine and What it is Used For

Sérum autologue ICH, collyre 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 intended for ocular use.

Sérum autologue ICH, collyre 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 as a concentration of 50% of serum, diluted with balanced salt solution (BSS).

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

Important risks of Sérum autologue ICH, collyre, 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 if necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Sérum autologue ICH, collyre is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Sérum autologue ICH, collyre 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 Sérum autologue ICH, collyre. 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).

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. While no confirmed cases of disease transmission have been reported in the literature for autologous serum eye drops, the theoretical risk is inherent to any blood-derived product. The evidence is weak but plausible.
Risk factors and risk groups	Patients receiving improperly screened or processed serum might be at higher risk. The autologous nature of the product provides an inherent safety margin, as the blood product is applied exclusively to the donor patient.
Risk minimisation measures	Routine risk communication: SmPC section: Mises en garde et précautions SmPC section: Contre-indications Package leaflet section: Quand le sérum autologue ICH, collyre ne doit-il pas être utilisé ? Mandatory serological screening (HIV, hepatitis B, hepatitis C, and syphilis) of all blood samples prior to processing with discard of any positive samples.
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, increasing the risk of ocular infection. The evidence is strong and supported by known risks associated with inadequate eye drop container systems. However, there is no evidence given in the literature whether a contamination during use with Novelia® bottles (equipped with a one-way valve system that maintains sterility throughout the period of use) has occurred.
Risk factors and risk groups	Patients with limited dexterity and poor hygiene practices might be 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 communication: SmPC section: Mise en garde et précautions SmPC section: Posologie / Mode d'emploi Package leaflet sections: Comment utiliser le sérum autologue ICH, collyre ? Package leaflet sections: A quoi faut-il encore faire attention ? Use of Novelia® eye drop bottles with one-way valve system.
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 or pre-existing iron deficiency. 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 communication: SmPC section: Contre-indications. Pre-donation screening with structured questionnaire (looking for symptoms or diagnosis of anaemia). Conservative blood collection volumes (up to 4 times per year, 60 to 150 ml per session, which is substantially lower than volumes collected from voluntary whole blood donors).
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 in the literature describe rare complications including eyelid eczema, immunoglobulin deposits in the cornea, peripheral corneal infiltrates, and scleral vasculitis with melting in patients with rheumatoid arthritis. Despite widespread clinical use over several decades, only 1–2 case reports have been documented for each of these complications.
Risk factors and risk groups	Patients with pre-existing ocular inflammation, autoimmune conditions (particularly rheumatoid arthritis), or hypersensitivity may be more susceptible to complications.
Risk minimisation measures	Routine risk communication: SmPC section Effets indésirables PL section Quels effets secondaires peut avoir Sérum autologue collyre ICH ? Identification of patients with known conditions and sensitivities.
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

Missing Information: Use in pregnant or breastfeeding women, paediatric patients, and patients using contact lenses	
Risk minimisation measures	Routine risk communication: SmPC section: Grossesse, Allaitement SmPC section: Posologie SmPC section: Interactions Package leaflet section: Le sérum autologue ICH, collyre peut-il être utilisé pendant la grossesse ou l'allaitement ? Package leaflet section: Comment utiliser le sérum autologue ICH, collyre ? Package leaflet section: De quoi faut-il tenir compte en dehors du traitement Patients under 18 years do not belong to the target population.
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry.

Missing Information: Long-term efficacy	
Risk minimisation measures	Routine risk communication: SmPC section: Posologie / Mode d'emploi.
Additional pharmacovigilance activities	Data collection from participation in the severe dry eye disease registry. The registry includes annual assessment of the Ocular Surface Disease Index (OSDI) and patient's subjective benefit compared to before therapy, enabling continuous monitoring of long-term efficacy.

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 Sérum autologue ICH, collyre.

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 and 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.