Hôpital ophtalmique Jules-Gonin

Swiss Summary of Risk Management Plan for Serum autologue HOJG 80%, Collyre

Active substance:	Human blood serum, autologous
Product concerned:	Sérum autologue HOJG 80%, collyre
Based on RPM Version 1.0	
Data lock point:	21.11.2025
Marketing Authorisation Holder:	Asile des aveugles, Lausanne

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 HOJG 80%, 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 HOJG 80%, collyre in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. The Asile des aveugles is fully responsible for the accuracy and correctness of the content of the published summary RMP of Sérum autologue HOJG 80%, collyre.

Summary of Risk Management Plan for Sérum autologue HOJG 80%, collyre (human blood serum, autologous)

This is a summary of the risk management plan (RMP) for Sérum autologue HOJG 80%, collyre. The RMP details important risks of Sérum autologue HOJG 80%, collyre, how these risks can be minimised, and how more information will be obtained about its risks and uncertainties (missing information).

Sérum autologue HOJG 80%, collyre summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sérum autologue HOJG 80%, collyre should be used.

This summary of the Sérum autologue HOJG 80%, 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 HOJG 80%, collyre RMP.

I. The Medicine and What it is Used For

Sérum autologue HOJG, collyre is authorised for the treatment of 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 human blood serum, autologous as the active substance and it is intended for ocular use.

In Dry Eye Disease not enough tear fluid is produced to create the protective film of moisture that normally coats the eye, or abnormalities in the tear fluid cause it to dry out too quickly. Without adequate protection from the tear fluid, the surface of the eye can develop damage and become inflamed, which can eventually lead to ulceration, infection, reduced vision and even sometimes to serious loss of vision due to the perforation of the eye

Sérum autologue HOJG, collyre is prepared form the patient's own blood, available in only one concentration: 80% serum diluted with balanced salt solution (BSS). The serum contains naturally occurring growth factors, vitamins, and proteins also present in tears. These components provide nutritional and growth factors to maintain cellular integrity during epithelial repair, as well as bactericidal components that can reduce the risk of contamination or infection.

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

Important risks of Sérum autologue HOJG 80%, 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 as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Sérum autologue HOJG 80%, 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 HOJG 80%, 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 HOJG 80%, 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).

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 risk is based on the biological nature of the product (substance of human origin). However, this risk is effectively mitigated through routine screening procedures. All blood samples undergo mandatory testing for HIV, hepatitis B, hepatitis C, and syphilis prior to processing
Risk factors and risk groups	Patients receiving improperly screened or processed serum might be at higher risk, but this is prevented by the adherence to the requirements for serology (see below). In addition, the blood product is applied exclusively to the donor patient.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections: Mises en garde, précautions d'emploi et contre-indications Package leaflet section: Quand et quelles précautions faut-il prendre lors de l'utilisation du sérum autologue, collyre ? Comment utiliser le Sérum autologue HOJG, collyre? Additioal risk minimisation measures: Routine screening procedures prior to processing. 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 patients may lead to contamination. The evidence is strong and supported by known risks of inappropriate 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: Posologie/Mode d'emploi. Package leaflet section: Comment utiliser le Sérum autologue HOJG, collyre ? Use of eye drop bottles (Novelia®) equipped with a one-way valve system that maintains sterility throughout the entire period of use. 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	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: Contre-indications. Pre-donation screening with structured questionnaire evaluating body weight (must exceed 50 kg) and screening for symptoms or diagnosis of anaemia. 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 of eyelid eczema, immunoglobulin deposits in the cornea, corneal peripheral infiltrates and scleral vasculitis with melting in patients with rheumatoid arthritis.
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: Effets indésirables Package leaflet section: Quels sont les effets indésirables potentiels du Sérum autologue HOJG, collyre ? Identification patients with known conditions and sensitivities. Additional risk minimisation measures: None.
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 minimisation measures: SmPC sections: Posologie/mode d'emploi, interactions, grossesse et allaitement. Package leaflet section: Le Sérum autologue HOJG, collyre peut-il être utilisé pendant la grossesse ou l'allaitement ? Comment utiliser Le Sérum autologue HOJG, collyre ?. Patients under 18 years do not belong to the target population. 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: Posologie/mode d'emploi. 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 Sérum autologue HOJG 80%, 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.