

Swiss Public Assessment Report

Manufacturing process for “Sérum autologue ICH, collyre”

International non-proprietary name:	autologous human serum
Pharmaceutical form:	eye drops, solution
Dosage strength(s):	50%
Route(s) of administration:	ocular
Marketing authorisation holder:	Institut Central des Hôpitaux
Marketing authorisation no.:	68590
Decision and decision date:	approved on 23 February 2026

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

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1 Terms, definitions, abbreviations

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
API	Active pharmaceutical ingredient
AS	Autologous serum
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
AUC _{0-24h}	Area under the plasma concentration-time curve for the 24-hour dosing interval
CI	Confidence interval
C _{max}	Maximum observed plasma/serum concentration of drug
CYP	Cytochrome P450
DDI	Drug-drug interaction
DED	Dry eye disease
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GI	Gastrointestinal
GLP	Good Laboratory Practice
HPLC	High-performance liquid chromatography
IC/EC ₅₀	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing authorisation holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Background information on the procedure

Autologous human serum eye drops were used as magistral-formula medicinal products for several years in the past. Following a change in the law in 2020, the manufacturing process for non-standardisable medicinal products, such as human serum eye drops, became subject to the authorisation requirement set out in Articles 33 and 34 TPO. The aim of subjecting the manufacturing processes for such products to approval of is to ensure patient-specific preparations of sufficient quality, safety and efficacy.

2.1 Applicant's request(s) and information regarding procedure

Authorisation of a manufacturing process for non-standardisable medicinal products in accordance with Articles 33 and 34 TPO

The applicant requested the authorisation of a manufacturing process for the non-standardisable medicinal product "Sérum autologue ICH, collyre" in accordance with Articles 33 and 34 TPO.

2.2 Indication and dosage

2.2.1 Requested indication

Symptomatic treatment of various severe conditions of the ocular surface, such as dry eye syndrome (or keratoconjunctivitis sicca) of various aetiologies (e.g. Sjögren's syndrome, graft-versus-host disease), neurotrophic keratopathy, injury to the cornea or conjunctiva (e.g. chemical or thermal burn), to limit the risk of unfavourable developments (ulceration, infection, loss of vision, perforation) and restore the integrity and clarity of the cornea. Tear substitute when standard treatment with artificial tears is not sufficient.

2.2.2 Approved indication

Sérum autologue ICH, collyre is used to treat dry eye syndrome (keratoconjunctivitis sicca) in patients aged 18 years and older who do not find relief from other authorised treatments.

2.2.3 Requested dosage

Summary of the requested standard dosage:

Adults: The frequency of use (generally from four times a day to once an hour) depends on the severity of the eye damage and must be determined by an ophthalmologist. For each application, instil one drop of ophthalmic solution into the conjunctival sac of the affected eye(s). The dose may be reduced or increased by the ophthalmologist depending on the results obtained.

Children and adolescents: Safety and efficacy have not been established in children and adolescents. Use in this population, on medical prescription, should therefore only be considered if the potential benefits outweigh the possible risks.

2.2.4 Approved dosage

(See appendix)

2.3 Regulatory history (milestones)

Application	5 July 2021
Submission of additional information	5 April 2022
Formal control completed	17 June 2022

List of Questions (LoQ)	18 January 2023
Response to LoQ	20 November 2023
LoQ 2	2 May 2024
Response to LoQ 2	5 December 2024
Preliminary decision	24 February 2025
Response to preliminary decision	26 June 2025
Preliminary decision 2	11 September 2025
Response to preliminary decision 2	1 December 2025
Labelling corrections and/or other aspects	2 February 2026
Response to labelling corrections and/or other aspects	6 February 2026
Final decision	23 February 2026
Decision	approval

3 Medical context

Dry eye disease (DED) is a complex multifactorial condition that is characterised by homeostatic disturbances of the ocular surface and tear film. Any disease or environmental factor that disrupts the function of the lacrimal functional unit by altering the volume or composition of the tear film will lead to a loss of ocular surface homeostasis.

A combination of tear film instability, hyperosmolarity and inflammation is triggered, which can result in progressive damage to the ocular surface and lead to neurosensory abnormalities with a significant impact on visual tasks.

Overall, DED has a significant impact on quality of life and functionality.

The prevalence of DED is high, with a variable reported range. European estimates in adult populations range from 10% to 30%¹.

The most widely used classification of dry eye is that proposed by TFOS DEWS II in 2017². It includes a clinical decision algorithm based on the pathophysiology of dry eye. In this report, the management of dry eye is based on a progressive approach divided into four stages depending on the severity of the pathology.

Autologous serum (AS) eye drops are recommended from stage 3 onwards when standard treatments have failed.

The AS mainly found in the literature is 20% AS, although higher concentrations (between 50% and 100%) are also used and described in the literature.

4 Quality aspects

4.1 Drug substance

The production of autologous serum eye drops started in 2010 and the medicinal process has been approved on the basis of long-standing use and the literature.

The drug substance of “Sérum autologue ICH, collyre” is a preparation of human blood obtained through autologous blood donation. According to the literature, autologous serum eye drops contain proteins, growth factors, vitamins, antioxidants, and electrolytes that closely mimic the biochemical properties of natural basal tears. The detailed composition of the product “Sérum autologue ICH, collyre” has not been determined, as the composition varies with each blood donation.

The manufacturing process includes blood collection, coagulation and centrifugation of the collected blood to obtain serum. Specifications include donor screening and visual inspection for haemolysis and lipemia.

No drug substance shelf life has been established since the drug substance is immediately introduced into the drug product manufacturing process.

4.2 Drug product

The finished drug product is 50% serum diluted with balanced salt solution. The product is intended for administration to the eye.

The manufacturing process involves aseptic dispensing into low-density polyethylene multidose container with a dropper device.

The specifications include sterility testing, container closure integrity and visual control for particles. A shelf-life of 6 months at $\leq -15^{\circ}\text{C}$ has been accepted based on literature data. The drug product is stored at $\leq -15^{\circ}\text{C}$ in original, unopened containers.

The proposed in-use shelf-life after thawing of 30 days at $2-8^{\circ}\text{C}$ has been accepted.

¹ Stapleton F, Alves M, Bunya VY, et al. TFOS DEWS II Epidemiology report. *Ocul Surf.* 2017;15:334–365.

² Jones L, Downie LE, Korb D, Benitez-Del-Castillo JM, Dana R, Deng SX, et al. TFOS DEWS II Management and Therapy Report. *Ocul Surf.* juill 2017;15(3):575-628.

4.3 Quality conclusions

The assessment of quality aspects focused on the primary safety concern, the risk of microbiological contamination, which necessitates aseptic manufacturing and sterility testing.

5 Nonclinical aspects

The proof-of-concept, pharmacokinetics and toxicology of the autologous serum product were not evaluated in conventional nonclinical studies. This was considered acceptable owing to a weight-of-evidence assessment that took account of clinical experience in the treatment of dry eye disease with autologous serum, the absence of reported serious adverse events in the clinical setting, the minimal expected systemic exposure after administration, as well as the autologous nature of the product, which limits the selection of relevant animal species. Additional animal studies are not expected to provide information beyond what is already known from clinical experience with autologous serum drug product.

6 Clinical aspects

6.1 Clinical pharmacology

N/A

6.2 Dose finding and dose recommendation

N/A

6.3 Efficacy

Multiple systematic reviews, meta-analyses and a Cochrane review³ have been published on the efficacy and safety of AS for the treatment of DED using products similar to “Sérum autologue ICH, collyre”.

The main evidence for the efficacy of AS in DED was based on a Cochrane review of five randomised clinical trials (92 participants) comparing AS with artificial tears or saline in individuals with DED of various origins (Sjögren's syndrome-related dry eye, non-Sjögren's syndrome dry eye, and postoperative dry eye induced by laser-assisted in situ keratomileusis (LASIK)). All five trials evaluated 20% AS.

This Cochrane review suggested that autologous serum had a short-term (two-week) beneficial effect on symptoms compared with artificial tears. However, this review found no evidence of any effect beyond two weeks of treatment.

An updated systematic literature was requested by Swissmedic and provided by the applicant (not published). The updated literature search identified two additional randomised controlled trials not included in the Cochrane review. No new evidence of clinical efficacy has been obtained from these studies. The overall conclusions of this literature review are consistent with the benefits suggested by the Cochrane review.

Other studies and meta-analyses have explored the long-term use of serum eye drops and suggest long-term efficacy, but it is uncertain whether these effects are transferrable to patient-relevant long-term benefits, since there is no robust evidence for long-term use and effect on quality of life. Moreover, there is no established definition of “long-term”, and there is no scientific consensus in the guidelines on the optimal duration of use of AS.

Nonetheless, the evidence is limited, with incomplete outcome reporting and heterogeneity among outcomes and follow-up periods. In addition, the data from clinical studies are highly heterogeneous, as procedural aspects of AS preparation, posology and patient populations differed significantly. Although there appears to be no consensus on the optimal concentration, most studies use 20%. Other published studies explore higher concentrations (50%, 80%, and undiluted) and suggest non-inferiority compared to the 20% concentration.

6.4 Safety

The primary safety consideration for AS is the risk of microbial growth during storage, because serum-based solutions are essentially growth media. Microbial contamination of AS containers has been reported with prolonged use (over 1 week at +4°C). The literature describes one case of an eye infection during treatment with AS caused by a contaminated AS container.

Four of the five studies in the Cochrane review did not report outcomes for adverse events or complications. One study reported conjunctivitis in two participants, with cultures showing no growth followed by resolution of the symptoms.

³ Pan Q, Angelina A, Marrone M, Stark WJ, Akpek EK. Autologous serum eye drops for dry eye. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD009327.

Among the other numerous published clinical studies and case reports on AS, the following complications have been reported (rarely): conjunctivitis, eyelid eczema, immunoglobulin deposits in cornea, corneal peripheral infiltrates, scleral vasculitis and scleral melting in patients with rheumatoid arthritis.

A Swiss study also specifically investigated the risk of infection using over 100,000 serum drop bottles over an observation period of 5 years and found three cases of infectious keratitis that could potentially have been associated with AS⁴.

These data suggest that AS may be safe for the treatment of DED.

6.5 Final clinical benefit risk assessment

Conclusive evidence on the safety and efficacy of AS in DED is limited by the relative lack of controlled studies with a sufficient level of evidence and long-term data.

A major difficulty faced by the review in endeavouring to obtain conclusive safety and efficacy results with a high level of evidence was heterogeneity among participant populations, interventions, and comparisons, as well as variations in the procedures performed to prepare AS.

The review suggested AS was beneficial to symptom resolution compared with artificial tears in the short term (two weeks). However, it also found no evidence of an effect beyond two weeks of treatment. Other studies, meta-analyses and a systematic review of the literature conducted by the applicant have explored the long-term use of serum eye drops and suggest long-term efficacy, but patient-relevant long-term benefits have not been clearly demonstrated. There is no solid evidence of efficacy in long-term use, and the effects on quality of life have not been investigated.

The generalisability of the results to the “Sérum autologue ICH, collyre” product could not be directly demonstrated.

AS seems to offer a hypothetical, unproven benefit over standard recommended therapies under the assumption that AS not only serves as a lacrimal substitute to provide lubrication, but contains other biochemical components that enable it to mimic natural tears. This therapy represents an additional burden for patients compared to conventional therapies, as it requires blood draws.

The major risk associated with the AS procedure is the risk of microbial growth during production, manipulation or storage. The possibility of eye infection (rarely reported in the literature) cannot be ruled out, particularly on a wounded surface in the process of healing, which can support microbial infestation. To minimise this risk, AS must be prepared under sterile conditions, and patients must strictly adhere to instructions for use and storage.

The Information for healthcare professionals, Patient information and risk management plan adequately mitigate this risk.

Other complications have been reported (rarely): conjunctivitis, eyelid eczema, immunoglobulin deposits in cornea, corneal peripheral infiltrates, scleral vasculitis and scleral melt in patients with rheumatoid arthritis.

At present, the benefit/risk profile for AS in DED patients recalcitrant to conventional therapy is considered positive. Authorisation was granted on the basis of medical need, the manageable toxicity profile, the benefit suggested (but not fully demonstrated) compared to standard of care and the major postmarketing conditions imposed on the MAH, which involve providing additional supporting data on identified uncertainties:

- Long term registry of DED patients recalcitrant to conventional therapy treated with AS
- Annual updates on any new information concerning the safety and efficacy of AS.

⁴ Sanak F et al. Five-Year Risk and Safety Profile of Autologous Serum Eye Drop Therapy. *Klin Monbl Augenheilkd.* 2024 Apr;241(4):388-391

7 Risk management plan summary

The RMP summaries contain information on the medicinal products' safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.

The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

8 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for “Sérum autologue ICH, collyre” was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo.ch).

Note:

The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. See the "Undesirable effects" section for advice on the reporting of adverse reactions.

Sérum autologue ICH, collyre

Composition

Active substances

Human serum, autologous

Excipients

Balanced saline solution (BSS), 50% V/V

Composition of BSS: sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium acetate trihydrate, sodium citrate dihydrate, sodium hydroxide and/or hydrochloric acid for pH adjustment, water for injections.

Pharmaceutical form and active substance quantity per unit

Eye drops, solution

An 11 ml multi-dose bottle of eye drops contains 8 ml of Sérum autologue ICH 50%, collyre.

Standard drops have a volume of 0.04 ml each.

Indications/Uses

Sérum autologue ICH, collyre is used to treat dry eye syndrome (keratoconjunctivitis sicca) in patients aged 18 years and older who do not find relief from other authorised treatments.

Dosage/Administration

Sérum autologue ICH, collyre should only be prescribed by an experienced ophthalmologist.

Adults (> 18 years)

The frequency of use (usually 4 times a day to once an hour) depends on the severity of the eye condition and should be determined by an ophthalmologist. For each application, instil 1 drop of ophthalmic solution into the conjunctival sac of the affected eye(s). The dose may be reduced or increased by the ophthalmologist depending on the results obtained.

The duration of treatment also depends on the type and severity of the condition and is determined by the ophthalmologist. Treatment can last from a few weeks to several years and must be regularly reviewed by an ophthalmologist at least once a year.

Children and adolescents

Sérum autologue ICH, collyre is not authorised for use in the paediatric population.

Method of administration

When starting a new bottle, the patient must check the label to ensure that their personal details (surname, first name, date of birth) are correct before using it for the first time. If the product is not intended for them, they must not use it under any circumstances and inform their pharmacist or doctor. When opening the bottle for the first time, the patient has to turn it upside down completely and leave it for about 1 minute to allow the tip to become thoroughly saturated. Before administering the product, the patient has to wash and dry their hands thoroughly. The bottle is open by unscrewing the cap. The patient has to tilt their head back, hold the bottle upright above the eye that needs to be treated and squeeze 1 drop of eye drops into the eye by gently pressing the sides of the soft plastic bottle. Direct contact between the bottle and the eye should be avoided to limit the risk of bacterial contamination of the product and/or damage to the surface of the eye. It is advisable to press the inner corner of the eye with finger for 1-2 minutes immediately after instillation to prevent the eye drops from flowing into the tear duct.

After use, the bottle must be properly closed and stored in the refrigerator (2-8°C).

A bottle can be used for up to 30 days after opening. It must then be discarded.

Contraindications

Sérum autologue ICH, collyre is contraindicated in patients with the following conditions:

- severe or untreated anaemia
- infectious conjunctivitis, infectious keratitis
- known history of contact hypersensitivity to silver: patients must not use this product as the drops may contain traces of silver from the container
- following infections: syphilis, hepatitis B, hepatitis C or HIV
- hypersensitivity to the active substance or to any of the excipients (see 'Composition').

Warnings and precautions

Sérum autologue ICH, collyre must only be used in the patient whose blood was used in its production. Therefore, the label has to be checked for accuracy of personal data (patient's surname, first name, date of birth) each time a new bottle is used. It must not be used by anyone else. If Sérum autologue ICH, collyre is administered by a third party, that person is advised to wear gloves for their own protection and that of the patient.

If adverse effects occur at the site of administration, such as irritation, pain, redness of the eye or changes in vision, or if the patient's condition worsens, it is necessary to consult an ophthalmologist and consider discontinuing treatment.

During use of the medicine, bacterial contamination of the bottle contents should be avoided.

Interactions

No clinically significant interactions have been reported so far, and no interaction studies have been conducted with Sérum autologue ICH, collyre.

When using another topical ophthalmic medication at the same time, an interval of at least 15 minutes should be respected between applications of the two medications.

Note for contact lens wearers

There are no reliable data on the use of Sérum autologue ICH, collyre in contact lens wearers. The use of Sérum autologue ICH, collyre with contact lenses is therefore not recommended.

Pregnancy, lactation

There are no adequate and well-controlled studies in pregnant/breastfeeding women. Therefore, Sérum autologue ICH, collyre should not be used during pregnancy and breastfeeding.

Effects on ability to drive and use machines

No relevant studies have been conducted. Sérum autologue ICH, collyre has a negligible effect on the ability to drive or operate machinery.

The administration of Sérum autologue ICH, collyre may cause temporary blurred vision, this should be taken into account when operating machines and driving in traffic. This blurred vision usually disappears a few minutes after the application of Sérum autologue ICH, collyre. Until vision has returned to normal, the above-mentioned activities should be avoided.

Undesirable effects

Adverse reactions are listed by MedDRA system organ class and frequency according to the following convention:

'very common' ($\geq 1/10$),

'common' ($\geq 1/100$ to $< 1/10$),

'occasional' ($\geq 1/1,000$ to $< 1/100$),

'rare' ($\geq 1/10,000$ to $< 1/1,000$),

'very rare' ($< 1/10,000$),

'unknown' (cannot be estimated from the available data).

Eye conditions

Common: vision may be temporarily blurred immediately after application, until the Sérum autologue ICH, collyre is evenly distributed over the eye. A temporary feeling of sticky eyes, irritation or burning may also occur immediately after application. These effects are temporary and have no consequences.

Rare: eyelid eczema, scleral vasculitis and lysis in cases of rheumatoid arthritis, immunoglobulin deposits in the cornea, peripheral corneal infiltrates, development of an eye infection during treatment due to a contaminated container.

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the EIViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

No cases of overdose have been reported so far.

Properties/Effects

ATC code

No ATC code attributed yet

Mechanism of action

Autologous serum eye drops are a suitable substitute for tears, as its physical and chemical properties (particularly viscosity) correspond to those of the tear film. It helps to reduce the symptoms associated with dry eye syndrome (discomfort, dryness, foreign body sensation, pain, redness, burning, stinging, sensitivity to light, blurred vision, itching), while increasing the moisturising properties of the tear film. Its therapeutic effect is based on the epitheliotropic effect of various substances present in blood serum. In healthy eyes, these substances are present in the tear film in varying concentrations. In cases of dry eye, their concentration decreases and often becomes insufficient. These substances include regenerative growth factors (such as Epidermal Growth Factor (EGF), Nerve Growth Factor (NGF) and Platelet-Derived Growth Factor (PDGF)), proteins (such as fibronectin, albumin and lysozymes) and vitamin A.

Growth factors support the cellular integrity of the corneal epithelium. EGF is a pleiotropic cytokine that can stimulate the proliferation, migration and adhesion of corneal epithelial cells during healing. Fibronectin has also been shown to play an essential role in the adhesion of the corneal epithelial layers and to participate in wound healing.

The serum also contains antibacterial components, such as IgG, lysozymes and complement, as well as nutrients.

The autologous serum is therefore used not only to moisturise the surface of the eye, but also to provide growth and nutritional factors (maintaining cell integrity during epithelial repair) and bactericidal components (reducing the risk of contamination or infection).

Pharmacodynamics

See "Mechanism of action"

Clinical efficacy

No clinical studies have been conducted with Sérum autologue ICH, collyre. Several systematic reviews of the literature, meta-analyses and a Cochrane review have been published on the efficacy and safety of autologous serum eye drops for the treatment of dry eyes (dry eye syndrome).

The main evidence for the efficacy of autologous serums in the treatment of dry eye syndrome comes from a Cochrane review (Pan et al, 2017) of five randomised clinical trials (92 participants): 20% autologous serum was compared with artificial tears or saline solution in patients with dry eye syndrome of various origins (particularly in association with Sjögren's syndrome or following laser surgery). This Cochrane study suggested temporary relief of symptoms for approximately two weeks with autologous serum compared to artificial tears.

However, this study found no evidence of efficacy after two weeks of treatment. Other studies, published with a lower level of evidence, have investigated the long-term use of autologous serum and suggested efficacy in long-term use, but the long-term benefits for patients are not clearly established. There is no strong evidence of long-term efficacy, and the effects on quality of life have not been studied.

The Institut Central des Hôpitaux uses a different concentration than that evaluated in the Cochrane review (20% autologous serum).

Although there does not appear to be expert consensus on the optimal concentration (TFOS DEWS III Management and Therapy Report), most studies use 20% autologous serum. Other published studies examine higher concentrations (50% and undiluted). These data are exploratory only and do not demonstrate the equivalence or superiority of higher concentrations of autologous serum compared to a 20% concentration.

Pharmacokinetics

Absorption

No data.

Distribution

No data.

Metabolism

No data.

Elimination

No data.

Kinetics in specific patient groups

No data.

Preclinical data

No preclinical safety studies have been conducted in animals.

Other information

Shelf life

This medicine should not be used after the date shown on the packaging after 'EXP'.

Shelf life after opening (thawing)

After thawing, the bottle of Sérum autologue ICH, collyre must be stored in the refrigerator (2°-8°C) in its packaging and used within 30 days. If it is not empty after 30 days, the remaining contents must be discarded and a new bottle opened.

Special precautions for storage

Store in the freezer (below -15°C) in its packaging.

Store in the refrigerator (2°-8°C) after thawing.

Keep out of the reach of children.

Use within 30 days after thawing.

Instructions for handling

Each bottle of Sérum autologue ICH, collyre must be used exclusively by the person who donated the blood used to produce it. If Sérum autologue ICH, collyre is to be administered by a third party, that person is advised to wear gloves.

The contents of the bottles of Sérum autologue ICH, collyre are sterile and contain no preservatives. In order to avoid contamination and guarantee the quality of the product throughout its shelf life, patients should observe the following points: do not touch any part of the body or any object with the tip of the dropper, close the bottle immediately after use and store the bottle in a refrigerator (2-8°C).

Before a new bottle can be used, it must be slowly thawed by leaving it in the refrigerator overnight. In addition, each time a new bottle is opened, the accuracy of the patient's personal details (surname, first name and date of birth) must be checked on the label before first use.

Authorisation number

68590 (Swissmedic)

Packs

Sérum autologue ICH 50%, collyre: 8 ml bottle [B]

The size of the package (number of bottles) depends on the volume of blood collected.

Marketing authorisation holder

Institut Central des Hôpitaux, Sion

Date of revision of the text

Février 2026