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Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

Manufacturing process for “Sérum autologue HOJG, collyre”

International non-proprietary name:	autologous human serum
Pharmaceutical form:	eye drops, solution
Dosage strength(s):	80%
Route(s) of administration:	ocular
Marketing authorisation holder:	Asile des aveugles
Marketing authorisation no.:	68575
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 HOJG, collyre” in accordance with Articles 33 and 34 TPO.

2.2 Indication and dosage

2.2.1 Requested indication

Severe dry eye disease that does not respond to conventional treatments (including dry keratoconjunctivitis, epithelial defects of the cornea, graft-versus-host disease after bone marrow transplantation, destruction of the lacrimal glands following radiotherapy, Sjogren's autoimmune disease or similar epitheliopathies); severe damage to the cornea.

2.2.2 Approved indication

HOJG Autologous Serum Eye Drops are used for the treatment of dry eye disease (keratoconjunctivitis sicca) in patients aged 18 years and older who have failed to respond to other approved therapies.

2.2.3 Requested dosage

Summary of the requested standard dosage:

The frequency of use depends on the severity of the damage to the ocular surface and is determined by the ophthalmologist. As a general rule, one drop is applied to the lower conjunctival sac of the affected eye at intervals ranging from three times a day to once an hour.

Children and adolescents: The use of this medication in children and adolescents is limited. Medical prescription should only be considered if the potential benefits outweigh the potential risks.

2.2.4 Approved dosage

(See appendix)

2.3 Regulatory history (milestones)

Application	29 June 2021
Submission of additional information	28 June 2022
Formal control completed	20 July 2022
List of Questions (LoQ)	18 January 2023
Response to LoQ	20 November 2023

LoQ 2	2 May 2024
Response to LoQ 2	30 December 2024
Preliminary decision	24 February 2025
Response to preliminary decision	24 June 2025
Preliminary decision 2	11 September 2025
Response to preliminary decision 2	28 November 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 2000 and the medicinal process has been approved on the basis of long-standing use and the literature.

The drug substance of “Sérum autologue HOJG, 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 HOJG, 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 80% 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 28 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 HOJG, 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 review 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 the 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 the cornea, corneal peripheral infiltrates, scleral vasculitis and scleral melt 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 draw 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 used 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 HOJG, 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 the 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 the 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 HOJG, 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 to allow rapid identification of new safety information. Healthcare professionals are required to report any suspected new or serious side effects. See the section on 'Side effects' for information on how to report side effects.

HOJG Autologous Serum, eye drops

Composition

Active substances

Autologous humanum serum

Excipients

Balanced Saline Solution (BSS), 20% 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 injection.

Pharmaceutical form and active substance quantity per unit

Eye drops, solution

One 11 ml multi-dose bottle of eye drops contains 5.0 ± 0.5 ml of HOJG 80% autologous Serum, eye drops.

Standard drops have a volume of 0.04 ml each.

Indications/Uses

HOJG Autologous Serum Eye Drops are used for the treatment of dry eye disease (keratoconjunctivitis sicca) in patients aged 18 years and older who have failed to respond to other approved therapies.

Dosage/Administration

HOJG autologous Serum eye drops should only be prescribed by an experienced ophthalmologist.

Usual dosage

The frequency of administration depends on the severity of the ocular surface disorder and is determined by the ophthalmologist. As a general rule, one drop is instilled into the lower conjunctival sac of the affected eye, ranging from three times daily to once an hour.

Duration of treatment

The duration of treatment also depends on the type and severity of the condition and is determined by the ophthalmologist. Treatment may extend from a few weeks to several years. Long-term treatment must be regularly re-evaluated by an ophthalmologist, at least once a year.

Paediatric population

HOJG autologous serum eye drops are not authorized for use in the paediatric population.

Route of administration

Before use, patients should be informed that:

- The vial must be thawed slowly at +2–8 °C (overnight in the refrigerator).
- Hands should be thoroughly washed and carefully dried before administration.
- The personal identification details (surname, first name, date of birth) on the label affixed to the bottle must be checked to ensure that they are correct. If the information is incorrect, the eye drops must not be used.

During use, patients should be advised that:

- Avoid any contact between the tip of the dropper bottle and the eye or surrounding structures to prevent microbial contamination.
- The tip of the bottle must not come into contact with any part of the body or any objects to prevent contamination.
- Incorrect handling of the eye drops may result in contamination with bacteria, which can lead to ocular infections. Use of contaminated eye drops may cause serious eye damage or even loss of vision.

Patients should also be informed that:

- The bottle must be tightly closed immediately after use and stored in a refrigerator between 2 and 8°C.
- The bottle must not be used more than 28 days after opening.

Contraindications

HOJG autologous serum eye drops are contraindicated in patients with the following conditions:

- Severe or untreated anaemia.
- Infectious conjunctivitis, infectious keratitis.
- Patients with a known history of contact hypersensitivity to silver should not use this product as the drops may contain traces of silver from the container.
- The 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

HOJG Autologous Serum Eye Drops may only be used for/by the person from whom the blood was collected and from which it was manufactured. Under no circumstances may it be used for/by a third party. Use by a third party could lead to the transmission of infectious diseases.

If HOJG Autologous Serum Eye Drops are administered by a third party, it is essential that this person wears gloves for their own protection and that of the patient.

The accuracy of the personal information on the bottle label (patient's first name, last name and date of birth) must be checked before each use.

Before each administration, ensure that the bottle content is clear and free from visible suspended particles.

When applying one or more other eye treatments, an interval of at least 15 minutes must be observed between administrations.

In the event of undesirable effects at the site of administration, such as irritation, pain or redness, or in case of visual disturbances, or if the patient's condition deteriorates, consultation with an ophthalmologist is required and discontinuation of treatment should be considered.

Interactions

No clinically relevant interactions are currently known. However, as no clinical interaction studies have been conducted to date, it is recommended that an interval of at least 15 minutes be observed between the administration of the products.

Although HOJG Autologous Serum eye drops are preservative-free, there are no reliable data on its use in contact lens wearers. Therefore, the administration of HOJG Autologous Serum eye drops is not recommended while wearing contact lenses.

Pregnancy, lactation

There are no adequate and well-controlled studies in pregnant/breastfeeding women. Therefore, HOJG Autologous Serum eye drops should not be used during pregnancy and breastfeeding.

Effects on ability to drive and use machines

No corresponding studies have been conducted.

HOJG Autologous Serum Eye Drops has a negligible influence on the ability to drive or operate machinery.

As administration of HOJG Autologous Serum Eye Drops may transiently cause blurred vision, this should be taken into account when operating machinery and driving in traffic. This blurred vision usually disappears a few minutes after the application of HOJG Autologous Serum Eye Drops. Activities mentioned above should be avoided until normal vision is restored.

Undesirable effects

Undesirable effects are listed by system organ class according to the MedDRA classification and by frequency according to the following convention:

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

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

'uncommon' ($\geq 1/1,000$ 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 disorders

Common: Immediately after administration, an unpleasant sensation of irritation and burning, a feeling of eyelid stickiness and blurred vision may be experienced. These effects are temporary and have no long-term consequences. If these symptoms persist, please discontinue treatment and consult your doctor or pharmacist.

Rare: The following undesirable effects have been reported in clinical trials: eyelid eczema, scleral vasculitis and lysis in rheumatoid arthritis, immunoglobulin deposits in the cornea, peripheral corneal infiltrates, and 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 to date.

Properties/Effects

ATC Code

No ATC Code assigned.

Mechanism of action

The therapeutic action of autologous serum eye drops in cases of severe damage to the surface of the eye is based on the epitheliotropic effect of various substances present in varying concentrations in the serum and tear film of a healthy eye. However, these substances are often deficient in cases of damage to the ocular surface. Among other things, these substances promote epithelial proliferation, differentiation and migration, such as growth factors (Epidermal Growth Factor (EGF), Transforming Growth Factor- α (TGF- α), Keratinocyte Growth Factor (KGF), Hepatocyte Growth Factor (HGF), Platelet-derived Growth Factor (PDGF), Fibroblast Growth Factor (FGF), Insulin-like Growth Factor (IGF), Nerve Growth Factor (NGF)), as well as proteins (such as fibronectin, albumin, lysozymes) and vitamin A.

Autologous serum eye drops are also a suitable tear substitute because their physicochemical properties (particularly their viscosity) are similar to those of the tear film.

In addition to its biochemical properties similar to physiological tears, autologous serum eye drops also contain components that promote healing. Fibronectin, which is present in quantities 10 to 15

times higher in serum than in tear fluid, plays a crucial role in the adhesion of epithelial layers to the cornea and is involved in wound healing.

Pharmacodynamics

See 'Mechanism of action'

Clinical efficacy

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

The main evidence for the efficacy of autologous serums in the treatment of dry eye comes from a Cochrane review (Pan et al. 2017) of 5 randomised clinical trials (92 participants); 20% autologous serums were compared to artificial tears or saline solution in patients with dry eye syndrome of various origins (including in association with Sjögren's syndrome and after laser surgery). This Cochrane review suggested temporary relief of symptoms for approximately two weeks with autologous serums compared to artificial tears.

However, this study found no evidence of efficacy after two weeks of treatment. Other published studies with a lower level of evidence have investigated the long-term use of autologous serums 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 Asile des aveugles 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 of autologous serum.

Pharmacokinetics

To date, there are no data available on the pharmacokinetics of autologous serum eye drops.

Absorption

To date, there are no data available on the absorption of HOJG autologous serum eye drops.

Distribution

To date, there are no data available on the distribution of HOJG autologous serum eye drops.

Metabolism

To date, there are no data available on the metabolism of HOJG autologous serum eye drops.

Elimination

To date, there are no data available on the elimination of HOJG autologous serum eye drops.

Kinetics in specific patient groups

To date, there are no data available on the kinetics in specific patient groups of HOJG autologous serum eye drops.

Preclinical data

No preclinical safety studies have been conducted in animals.

Other information

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Effects on diagnostic methods

To date, there are no data on the influence of HOJG autologous serum eye drops on diagnostic methods.

Shelf life

This medicinal product should not be used beyond the date indicated after "EXP" on the packaging.

Shelf life after opening (thawing)

After thawing, the bottle of HOJG Autologous Serum Eye Drops must be stored in the refrigerator (2°-8°C) in its original packaging and used within 28 days. If it is not empty after 28 days, the remaining contents must be discarded and a new bottle opened.

Special precautions for storage

Store in a freezer (below -15°C).

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

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

Keep the container closed.

Keep out of the reach of children.

Use within 28 days after thawing.

Instructions for handling

The eye drop bottle must be thawed slowly at 2°-8°C (overnight in the refrigerator) before use.

If HOJG Autologous Serum Eye Drops are to be administered by a third party, that person is advised to wear gloves.

The contents of the bottles of HOJG Autologous Serum Eye Drops are sterile and contain no preservatives. In order to avoid contamination and ensure the quality of the product throughout its shelf life, patients should take care to 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 the refrigerator (2°-8°C).

Authorisation number

68578 (Swissmedic)

Packs

HOJG 80% autologous serum, eye drops: 5 ml bottle [B]

Package size depends on the volume of blood collected.

Marketing authorisation holder

Asile des aveugles, Lausanne

Date of revision of the text

February 2026