swissmedic

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Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

Manufacturing process for “Serum autolog USZ, Augentropfen”

International non-proprietary name:	autologous human serum
Pharmaceutical form:	eye drops, solution
Dosage strength(s):	50%, 100%
Route(s) of administration:	ocular
Marketing authorisation holder:	ZüriPharm AG
Marketing authorisation no.:	68544
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.

Table of contents

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
$AUC_{0\text{-}24h}$	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 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 "Serum autolog USZ, Augentropfen" in accordance with Articles 33 and 34 TPO.

2.2 Indication and dosage

2.2.1 Requested indication

For topical application in various forms of dry eye, with qualitative wetting disorder, with or without systemic disease (such as primary or secondary Sjögren's syndrome, graft versus host disease after allogeneic stem cell transplantation, etc.), neutrophil surface disorders, with or without epithelial defect, with or without corneal ulcer or chemical burns.

2.2.2 Approved indication

Serum autolog USZ, eye drops are indicated for the treatment of dry eye disease (keratoconjunctivitis sicca) in patients aged 18 years and older who do not achieve adequate symptom control with other approved therapies.

2.2.3 Requested dosage

Summary of the requested standard dosage:
Adults: The frequency of application depends on the severity of the eye surface problem and is determined by an ophthalmologist. As a rule, one drop is applied to the lower conjunctival sac of the affected eye between four times a day and once every hour. The dosage can be increased or decreased by the ophthalmologist, depending on the ophthalmological findings. The duration of use depends on the ophthalmologist's prescription. Treatment is often given over a long period and must be regularly monitored by an ophthalmologist.
Children and adolescents: This medicine has limited use in children and adolescents. It should only be used as directed by a doctor if the potential benefits outweigh the possible risks.

2.2.4 Approved dosage

(See appendix)

2.3 Regulatory history (milestones)

Application	14 June 2021
Submission of additional information	22 June 2021
Formal control completed	9 May 2022

List of Questions (LoQ)	18 January 2023
Response to LoQ	13 November 2023
LoQ 2	2 May 2024
Response to LoQ 2	28 November 2024
Preliminary decision	24 February 2025
Response to preliminary decision	23 June 2025
Preliminary decision 2	11 September 2025
Response to preliminary decision 2	26 November 2025
Labelling corrections and/or other aspects	2 February 2026
Response to labelling corrections and/or other aspects	11 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 2017[2]. 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 2009 and the medicinal process has been approved on the basis of long-standing use and the literature.
The drug substance of “Serum autolog USZ, Augentropfen” 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 “Serum autolog USZ, Augentropfen” 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 100% serum or 50% serum diluted with balanced salt solution. The product is intended for administration to the eye.
The manufacturing process involves aseptic dispensing into polyvinylchloride 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 ≤ -15°C has been accepted based on literature data. The drug product is stored at ≤ -15°C in original, unopened containers.
The proposed in-use shelf-life after thawing of 24 hours at 2-8°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 review[3] have been published on the efficacy and safety of AS for the treatment of DED using products similar to “Serum autolog USZ, Augentropfen”.
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 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 AS[4].
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 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 “Serum autolog USZ, Augentropfen” 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 “Serum autolog USZ, Augentropfen” 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 allows for the rapid identification of new information regarding its safety. Healthcare professionals are requested to report any suspected new or serious adverse reactions. For information on reporting adverse reactions, please refer to the section “Undesirable Effects.”

Serum autolog USZ, eye drops

Composition

Active substances

Serum humanum autologum

Excipients

Balanced Salt Solution, 50% v/v (BSS).
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 q.s.

Pharmaceutical form and active substance quantity per unit

Eye drops, solution
Daily doses: available in resealable transparent daily vials.
One daily vial contains 0.75 mL to 2.50 mL of *Serum autolog USZ 100%, eye drops* or *Serum autolog USZ 50%, eye drops.*
Standard drops have a volume of 0.031 mL each.

Indications/Uses

Serum autolog USZ, eye drops are indicated for the treatment of dry eye disease (keratoconjunctivitis sicca) in patients aged 18 years and older who do not achieve adequate symptom control with other approved therapies.

Dosage/Administration

Serum autolog USZ, eye drops may only be prescribed by a qualified ophthalmologist.

Adults
Recommended dosage
The frequency of administration depends on the severity of the ocular surface disorder and is determined by the ophthalmologist. Typically, one drop is applied to the lower conjunctival sac of the affected eye 4 times daily up to a maximum of once every hour. The dosage may be adjusted, either reduced or increased, depending on the severity of the ophthalmological findings.

The content of the daily vial is matched to the prescribed frequency of administration and usually provides a day's treatment.

Duration of treatment

The duration of use is determined by the prescribing ophthalmologist. Treatment is often carried out over an extended period and requires regular ophthalmologic monitoring, with a minimum frequency of once annually.

Route of administration

Before use, patients have to be informed that:

- The daily vial must be thawed slowly at 2 - 8°C (overnight in the refrigerator).
- Hands must be washed thoroughly and dried completely before use.
- The personal information (name, first name, date of birth) on the label of the daily vial must be checked for accuracy. If the information is incorrect, *Serum autolog USZ, eye drops* must not be used.

During use, patients should be made aware that:

- As the unopened daily vial contains sterile autologous serum without preservatives, contact between the daily vial tip and the eye, other body parts, or surrounding surfaces must be avoided to prevent contamination of the eye drops.
- Contact of the dropper tip with the eye can cause injuries to the ocular surface.
- Improper handling *of Serum autolog USZ, eye drops* can lead to bacterial contamination, which may result in eye infections. Using contaminated eye drops can cause severe eye damage or even loss of vision.

Patients should also be informed that:

- Immediately after use, the daily vial must be closed by snapping on the protective cap and stored refrigerated at 2 - 8°C until the next application.
- Once thawed, the daily vial must not be used for more than 24 hours.

Children and adolescents

Serum autolog USZ, eye drops are not approved for use in the pediatric population.

Contraindications

Serum autolog USZ, eye drops are contraindicated in patients with:

- Severe or untreated anemia.
- Syphilis, hepatitis B, hepatitis C, or HIV infection.
- Infectious conjunctivitis or infectious keratitis.
- Hypersensitivity to the active substance or any of the excipients in the eye drops.

Warnings and precautions

Serum autolog USZ, eye drops must be used exclusively by the patient from whose blood they were prepared. Therefore, before each application, the label on the daily vial must be checked for accuracy of the personal information (name, first name, date of birth of the patient). They must not be used by any other person.
If the administration of *Serum autolog USZ, eye drops* is performed by a third person on the patient, this person must wear medical gloves for their own protection.
If adverse events occur at the site of administration - such as eye irritation, pain, redness, or changes in vision - or if the patient's condition worsens, an ophthalmologist should be consulted, and discontinuation of treatment should be considered.

Interactions

No clinically relevant interactions have been reported to date. Clinical interaction studies have not been conducted.
When administering another ophthalmic medicinal product, a minimum interval of 15 minutes should be observed between applications.

Note for contact lens wearers
There is no robust data on the use of *Serum autolog USZ, eye drops* in contact lens wearers. Administration of *Serum autolog USZ, eye drops* is not recommended while wearing contact lenses. Potential risks include: The protein-rich autologous serum eye drops may clog the pores of monthly or yearly corrective contact lenses, impairing oxygen supply to the cornea. Microbial contamination of the lens may occur due to the high protein content of the autologous serum eye drops. The lens itself may prevent uptake of the serum components by the eye, thereby reducing the therapeutic effect.

Pregnancy, lactation

There are no adequate and well-controlled studies in pregnant or breastfeeding women. Therefore, *Serum autolog USZ, eye drops* should not be used during pregnancy or lactation.

Effects on ability to drive and use machines

No specific studies have been conducted. *Serum autolog USZ, eye drops* have a negligible effect on the ability to drive or operate machinery. Immediately after instillation and until the drops are evenly distributed on the eye, temporary blurred vision may occur. This should be taken into account when operating machinery or driving. Impairment usually resolves within a few minutes after application. Until normal vision is restored, the above activities should be avoided.

Undesirable effects

Adverse effects are classified according to the MedDRA system organ classes and are listed by frequency using the following convention:

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Eye disorders:
Common: Immediately after administration, patients may experience mild irritation and burning, a sensation of eyelid stickiness, and blurred vision. These effects are transient and have no long-term consequences.

Rare: The following adverse reactions have been reported in clinical studies: eyelid eczema, scleral vasculitis and lysis in patients with rheumatoid arthritis, immunoglobulin deposits in the cornea, peripheral corneal infiltrates, and eye infections during treatment with eye drops due to a contaminated eye drop 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 ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

No cases of overdose have been reported.

Properties/Effects

ATC code

No ATC code has been assigned.

Mechanism of action

According to the literature, the therapeutic effect of autologous serum eye drops in severe ocular surface disorders is based on the epitheliotrophic effect of various substances naturally present in blood serum. These substances are also found in the tear film of a healthy eye in varying concentrations. In cases of ocular surface disorders, their concentration is often insufficient. These include regenerative growth factors (such as EGF, NGF, PDGF), proteins (such as fibronectin, albumin, lysozyme), and vitamin A. In addition to their tear-like biochemical properties, autologous serum eye drops also provide nutritional components. Therefore, they are used not only to hydrate the ocular surface but also to supply nutrients and growth factors that help maintain cellular integrity

during epithelial repair. Autologous serum eye drops are also a suitable tear substitute, as their physicochemical properties, particularly viscosity, are adapted to the parameters of the natural tear film.

Pharmacodynamics

See “Mechanism of Action.”

Clinical efficacy

No clinical studies have been conducted with *Serum autolog USZ, eye drops*.
Several systematic literature reviews, meta-analyses, and a Cochrane review have been published on the efficacy and safety of autologous serum eye drops for the treatment of dry eye (dry eye syndrome, Sicca syndrome).
The main evidence for the efficacy of autologous serum eye drops in dry eye comes from a Cochrane review (Pan et al., 2017) of five randomized clinical trials (92 participants). In these studies, 20% autologous serum eye drops were compared with artificial tears or saline in patients with Sicca syndrome of various causes (including Sjögren’s syndrome and post-laser surgery).
This Cochrane review indicated a temporary short-term relief of symptoms over approximately two weeks with autologous serum eye drops compared to artificial tears. However, no effect was observed beyond the two-week treatment period in this review.
Other published studies with lower levels of evidence have investigated long-term use of serum eye drops and suggest efficacy with prolonged application. Nevertheless, patient-relevant long-term benefits are not clearly established. Solid evidence for efficacy with long-term use is lacking, and the impact on quality of life has not been studied.

ZüriPharm AG uses a different concentration than the 20% autologous serum eye drops evaluated in the Cochrane review. Although there is no apparent consensus among experts regarding the optimal concentration (TFOS DEWS III Management and Therapy Report), most studies use 20% autologous serum eye drops. Other published studies have investigated higher concentrations (50% and undiluted). These data are exploratory only and do not provide clear evidence of equivalence or superiority of higher-concentration serum eye drops compared to 20% autologous serum eye drops.

Pharmacokinetics

Absorption

Not studied.

Distribution

Not studied.

Metabolism

Not studied.

Elimination

Not studied.

Kinetics in specific patient groups

Not studied.

Preclinical data

No preclinical safety studies have been conducted in animals.

Other information

Incompatibilities

As no compatibility studies are available, this medicine must not be mixed with other medications.

Effects on diagnostic methods

Not studied.

Shelf life

The medicine should only be used until the expiration date (“EXP”) indicated on the packaging.
Shelf life after opening (thawing)
After thawing, stable for 24 hours in a refrigerator (2 - 8 °C).

Special precautions for storage

Store frozen (below -15 °C).
After thawing, store in a refrigerator (2 - 8 °C).
Keep in the original packaging.
Keep the container tightly closed.
Keep out of reach of children.

Instructions for handling

For use, daily vial must be thawed slowly (in the refrigerator).
To maintain sterility, do not touch the tip with your hands or the eye.
Unused medicine or waste material must be disposed of in accordance with national regulations.

Authorisation number

68544 (Swissmedic)

Packs

Serum autolog USZ 100%, eye drops daily vials of 0.75–2.50 ml [B]

Serum autolog USZ 50%, eye drops daily vials of 0.75–2.50 ml [B]:

The package size depends on the volume of blood collected.

Marketing authorisation holder

ZüriPharm AG, Schlieren

Date of revision of the text