swissmedic

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Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

Manufacturing process for “Serum autolog Blutspende Zürich, Augentropfen”

International non-proprietary name:	autologous human serum
Pharmaceutical form:	eye drops, solution
Dosage strength(s):	100%
Route(s) of administration:	ocular
Marketing authorisation holder:	Stiftung Zürcher Blutspendedienst SRK
Marketing authorisation no.:	68573
Decision and decision date:	approved on 24 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 Blutspende Zürich, Augentropfen" in accordance with Articles 33 and 34 TPO.

2.2 Indication and dosage

2.2.1 Requested indication

Dry eye (keratoconjunctivitis sicca), persistent epithelial defects of the cornea and conjunctiva, neurotrophic corneal disease; for autologous or allogeneic use.

2.2.2 Approved indication

Serum autolog Blutspende Zürich, eye drops are used to treat dry eye (keratoconjunctivitis sicca) in patients aged 18 years and over who do not become symptom-free with any other approved therapy.

2.2.3 Requested dosage

Summary of the requested standard dosage:
The treating physician will determine the frequency of application and the duration of treatment.

2.2.4 Approved dosage

(See appendix)

2.3 Regulatory history (milestones)

Application	29 June 2021
Submission of additional information	31 May 2022
Formal control completed	15 June 2022
List of Questions (LoQ)	18 March 2023
Response to LoQ	14 August 2023
LoQ 2	17 November 2023
Response to LoQ 2	10 May 2024
Preliminary decision approval	9 August 2024
Response to preliminary decision approval	25 November 2024
Preliminary decision 2 rejection	24 February 2025

Response to decision 2 rejection	4 June 2025
Preliminary decision 3 approval	2 September 2025
Response to preliminary decision 3 approval	19 November 2025
Labelling corrections and/or other aspects	2 February 2026
Response to labelling corrections and/or other aspects	11 February 2026
Labelling corrections and/or other aspects 2	17 February 2026
Response to labelling corrections and/or other aspects 2	23 February 2026
Final decision	24 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 was initiated in 2020. The medicinal process has been approved on the basis of longstanding use and published scientific literature.
The drug substance of “Serum autolog Blutspende Zürich, Augentropfen” consists of a human serum preparation 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 tears. The detailed composition of the product “Serum autolog Blutspende Zürich, 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 the 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. The product is intended for administration to the eye.
The manufacturing process involves 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 Blutspende Zürich, 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 one 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 any 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 Blutspende Zürich, 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 Blutspende Zürich, 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 will allow for the quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. For information on how to report adverse reactions, see the section "Adverse Reactions".

Serum autolog Blutspende Zürich, eye drops

Composition

Active substances

Autologous human blood serum

Excipients

None

Pharmaceutical form and active substance quantity per unit

Eye drops, solution
Daily doses: available exclusively as resealable, transparent eye drop vials.
1.5 ml eye drop vial with plastic pipette tip. One eye drop bottle contains 1.0–1.5 ml of 100% Serum autolog Blutspende Zürich, eye drops.
Standard drops have a volume of 0.025–0.050 ml each.

Indications/Uses

Serum autolog Blutspende Zürich, eye drops are used to treat dry eye (*keratoconjunctivitis sicca*) in patients aged 18 years and over who do not become symptom-free with any other approved therapy.

Dosage/Administration

Serum autolog Blutspende Zürich, eye drops may only be prescribed by a qualified ophthalmologist.
Usual dosage
The frequency of application depends on the severity of the eye's surface condition and is determined by an ophthalmologist. Generally, one drop is applied to the lower conjunctival sac of the affected eye four times daily, up to a maximum of one drop per hour. The dosage may be reduced or increased by the ophthalmologist depending on the extent of the eye examination findings.
The content of the vial is usually sufficient for one day's treatment.
Duration of treatment
The duration of treatment 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 should be regularly reassessed by an ophthalmologist.
Type of application
Before first use, patients should be informed of the following points:

- Serum autolog Blutspende Zürich, eye drops can be stored in the freezer at a maximum temperature of -15°C for 6 months.
- After thawing, they can be stored in the refrigerator at 2-8°C for 24 hours.
- Serum autolog Blutspende Zürich, eye drops must not be used after the expiration date.

Before using the eye drops, hands should be thoroughly cleaned to prevent germs from entering the vial.

Only one vial should be removed from the packaging at a time. Thaw the vial in your hand.

- Opening: The vial cap is opened by gently twisting.
- Application: Turn the vial upside down and hold it near the inner corner of the eye. Then, gently apply light pressure to the vial with your fingers and dispense one drop into the inner corner of the affected eye. Should a drop accidentally leak from the eye, another drop can be placed in the corner of the eye. Care should be taken to avoid touching the opening of the eye drop bottle.
- Closing: After administering the eye drops, close the eye drop bottle by replacing the cap and store it in the refrigerator at 2-8°C until the next use.

Children and adolescents

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

Contraindications

Serum autolog Blutspende Zürich, eye drops are contraindicated in patients in the following cases:
- Severe or untreated anemia.
- Syphilis, hepatitis B, hepatitis C, or HIV infection.
- Infectious conjunctivitis and infectious keratitis.
- Hypersensitivity to the active ingredient or any of the excipients in the eye drops.

Warnings and precautions

Serum autolog Blutspende Zürich, eye drops may only be used by the patient from whose blood they were prepared. No other person may use Serum autolog Blutspende Zürich, eye drops. Before using the eye drops, ensure that the contents are clear, not cloudy, and free of any sediment. If such changes are nevertheless noticeable, or if adverse events such as eye irritation, pain, redness, or changes in vision occur at the application site, or if the patient's condition worsens, consult an ophthalmologist and consider discontinuing treatment. The affected bottle of eye drops should not be discarded but returned to the Zurich Blood Donation Service SRK Foundation for further investigation. If the Serum autolog Blutspende Zürich, eye drops are not administered by the patient themselves, medical gloves must be worn.

Interactions

No interactions with other active ingredients, foods, or stimulants are known. No relevant studies have been conducted. However, it is recommended to maintain an interval of at least 15 minutes between the administration of any two products when using one or more other eye treatments.

Contact lens wearers
Although Serum autolog Blutspende Zürich, eye drops do not contain preservatives, there is no reliable data on their use in contact lens wearers. Therefore, the administration of Serum autolog Blutspende Zürich, eye drops is not recommended for contact lens wearers.

Pregnancy, lactation

There are no adequate and well-controlled studies on pregnant/breastfeeding women. Therefore, Serum autolog Blutspende Zürich, eye drops should not be used during pregnancy and breastfeeding.

Effects on ability to drive and use machines

No relevant studies have been conducted. Serum autolog Blutspende Zürich, eye drops have a negligible influence on the ability to drive or operate machinery. Blurred vision may occur temporarily after applying Serum autolog Blutspende Zürich, eye drops until they are distributed across the eye. This should be taken into account when operating machinery and driving. The impairment usually disappears a few minutes after applying Serum autolog Blutspende Zürich, eye drops. The activities mentioned above should be avoided until vision has returned to normal after application.

Undesirable effects

The adverse effects are listed according to the organ system classes of the MedDRA classification and according to frequency according to the following convention:
"very common" (≥1/10),
"common" (≥1/100 to <1/10),
"uncommon" (≥1/1000 to <1/100),
"rare" (≥1/10’000 to <1/1000),
"very rare" (<1/10’000),
"not known" (cannot be estimated from the available data).

Eye disorders:
Common: Immediately after administration, an unpleasant sensation of irritation and burning, a feeling of the eyelids sticking together, and blurred vision may occur. These effects are temporary and have no long-term consequences.
Rare: The following adverse reactions have been reported in clinical trials: eyelid eczema, scleral vasculitis and lysis in rheumatoid arthritis, immunoglobulin deposits in the cornea, peripheral corneal infiltrates, and eye infection 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 assigned.

Mechanism of action

According to literature, the therapeutic effect of autologous serum eye drops in cases of severe damage to the ocular surface is based on the epitheliotrophic effect of various substances that occur in different concentrations in the serum and tear film of a healthy eye. These substances promote, among other things, the proliferation, differentiation, and migration of epithelia, particularly 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, and lysozyme) and vitamin A.
In addition to biochemical properties similar to those of physiological tear fluid, autologous serum eye drops also contain components that contribute to wound healing. Fibronectin, which is present in serum in 10 to 15 times higher concentrations 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 trials have been conducted with autologous serum eye drops from the Zurich blood donation center.
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 serum eye drops in dry eye is based on a Cochrane review (Pan et al. 2017) of five randomized clinical trials (92 participants). Autologous serum eye drops (20%) were compared with artificial tears or saline solution in patients with sicca syndrome of various causes (including those associated with Sjögren's syndrome and those following laser surgery).
This Cochrane review suggested temporary, short-term symptom relief for approximately two weeks with serum eye drops compared to artificial tears. However, this study found no evidence of efficacy following two weeks of treatment.

Other published studies with lower levels of evidence have investigated the long-term use of serum eye drops and suggest efficacy with long-term use, but patient-relevant long-term benefits have not been clearly demonstrated. Solid evidence for efficacy with long-term use is lacking, and the impact on quality of life has not been investigated.
The Zurich Blood Transfusion Service SRK Foundation uses a different concentration than the 20% autologous serum eye drops evaluated in the Cochrane review.
Although there appears to be no expert consensus regarding the selection of the optimal concentration (TFOS DEWS III Management and Therapy Report), most studies use 20% autologous serum eye drops. Other published studies investigate higher concentrations (50% and undiluted). These data are only exploratory and do not clearly demonstrate the equivalence or superiority of higher serum eye drop concentrations compared to a concentration of 20% autologous serum eye drops.

Pharmacokinetics

Absorption

Not specified.

Distribution

Not specified.

Metabolism

Not specified.

Elimination

Not specified.

Kinetics in specific patient groups

Not specified.

Preclinical data

No preclinical safety studies were conducted in animals.

Other information

Incompatibilities

Since no compatibility studies have been carried out, this medicine must not be mixed with other medicines.

Effects on diagnostic methods

No effects on diagnostic methods are known. No relevant studies have been conducted.

Shelf life

The medicine must only be used until the date marked "EXP" on the packaging.
Shelf life after opening (thawing):
Once thawed, it can be stored in the refrigerator (2–8°C) for 24 hours.

Special precautions for storage

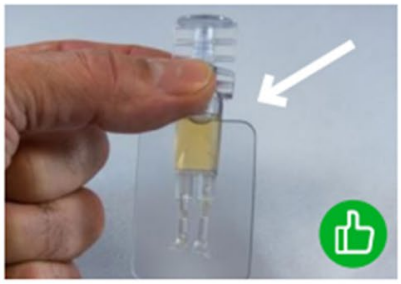
Store frozen (below -15°C).
Once opened, store in the refrigerator (2–8°C).
Store in the original packaging.
Keep the container tightly closed.
Keep out of reach of children.

Instructions for handling

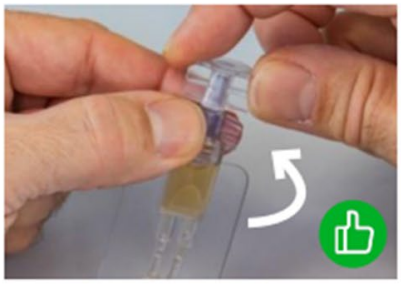
Serum autolog Blutspende Zürich, eye drops contain no preservatives. The dropper tip of the vial must not come into contact with any surface, as this can contaminate the eye drops. Direct contact of the dropper tip with the eye can cause injury to the ocular surface.

Before using the eye drops, wash your hands thoroughly with soap. Lather all areas of your hands for at least 30 seconds (including thumbs, between fingers, backs of hands, and fingernails). Dry your hands with a dry, clean towel and then disinfect them with an alcohol-based hand sanitizer. After use, the vial must be resealed with the cap and stored in the refrigerator at 2–8°C until the next use.

Figure 1: How do I open the vial?



1. **Hold the bottle below the cap with one hand...**



2. **...with the other hand, loosen the lid by turning it...**

3. **… and then pull upwards.**

When opening, do not press on the liquid area of the bottle...

...and don't bend the cap.

Figure 2: How do I close the vial?

To close, place the cap on and then slide it in.

Unused medicinal product or waste material must be disposed of in accordance with national requirements.

Authorisation number

68573 (Swissmedic)

Packs

Serum autolog Blutspende Zürich 100%, eye drops:

Packs of 30 ophthalmic vials of 1.0 – 1.5 ml each.

The number of packs depends on the volume of blood drawn.

Marketing authorisation holder

Stiftung Zürcher Blutspendedienst SRK, Zürich

Date of revision of the text

February 2026