swissmedic

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Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

Manufacturing process for “Serum autolog LUKS, 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:	LUKS Spitalbetriebe AG
Marketing authorisation no.:	68578
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 LUKS, Augentropfen" in accordance with Articles 33 and 34 TPO.

2.2 Indication and dosage

2.2.1 Requested indication

For lubricating, cleaning and nourishing the ocular surface in various forms of dry eye (sicca syndrome, keratoconjunctivitis, epithelial defects, corneal ulcer in chronic polyarthritis, Sjögren's syndrome, neurotrophic keratopathy, graft-versus-host disease, chemical burns, etc.), as well as for special indications, e.g. severe corneal diseases, graft-versus-host diseases of the eyes after stem cell transplants and poorly healing injuries to the eyes.

2.2.2 Approved indication

Serum autolog LUKS, eye drops are used for the treatment of dry eye disease (keratoconjunctivitis sicca) in patients aged 18 years and older who are not symptom-free with another approved therapy.

2.2.3 Requested dosage

Summary of the requested standard dosage:
Adults: The drops are applied to the affected eye every hour or at least five times a day and distributed by blinking.
Children and adolescents: The use of autologous serum eye drops in children and adolescents has not yet been systematically tested. They should only be used as prescribed by a doctor if the risk-benefit profile permits.
The duration of therapy depends on the severity of the problem.

2.2.4 Approved dosage

(See appendix)

2.3 Regulatory history (milestones)

Application	30 June 2021
Submission of additional information	31 March 2022
Formal control completed	5 July 2022
List of Questions (LoQ)	18 January 2023

Response to LoQ	20 November 2023
LoQ 2	2 May 2024
Response to LoQ 2	4 December 2024
Preliminary decision	24 February 2025
Response to preliminary decision	23 June 2025
Preliminary decision 2	11 September 2025
Response to preliminary decision 2	27 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 at Cantonal Hospital Lucerne was started in 2008 and the medicinal process has been approved on the basis of long-standing use and the literature.
The drug substance of “Serum autolog LUKS, 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 LUKS, 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 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 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 ≤ -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 4 weeks 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 LUKS, 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 an 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, vasculitis and scleral melt in patients with rheumatoid arthritis.
A Swiss study also specifically investigated the risk of infection with 752 patients treated over an observation period of 5 years and found three cases of infectious keratitis that could potentially have been associated with AS[4].
Overall, these data suggest that AS may be safe for the treatment of DED.

6.5 Final clinical benefit risk assessment

Conclusive evidence on the safety and efficacy of AS in DED is limited by the relative lack of controlled studies with a sufficient level of evidence and long-term data.
A major difficulty faced by the review in endeavouring to obtain conclusive safety and efficacy results with a high level of evidence was heterogeneity among participant populations, interventions, and comparisons**,** as well as variations in the procedures performed to prepare AS.
The review suggested AS was beneficial to symptom resolution compared with artificial tears in the short term (two weeks). However, it also found no evidence of an effect beyond two weeks of treatment.
An updated systematic literature review conducted by the applicant (not published) found no new evidence of clinical efficacy, with conclusions consistent with the benefits suggested by the Cochrane review. Other studies 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 available efficacy and safety results to the “Serum autolog LUKS, 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 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 LUKS, 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 enables quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. For guidance on reporting adverse reactions, see section “Undesirable effects”.

Serum autolog LUKS, eye drops

Composition

Active substances

Human blood serum, autologous.

Excipients

Serum autolog LUKS 50%, eye drops contain balanced salt solution, 50% v/v (BSS), as an excipient.
BSS composition:
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 q.s.

Pharmaceutical form and active substance quantity per unit

Eye drops, solution.
An 11-ml multidose eye-drop bottle contains 5.0 ± 0.5 ml of *Serum autolog LUKS 100%, eye drops* or *Serum autolog LUKS 50%, eye drops*.
Standard drops contain 0.04 ml each.

Indications/Uses

Serum autolog LUKS, eye drops are used for the treatment of dry eye disease (keratoconjunctivitis sicca) in patients aged 18 years and older who are not symptom-free with another approved therapy.

Dosage/Administration

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

Usual dosage

Frequency depends on the severity of ocular surface damage and is determined by the ophthalmologist. Typically, one drop is instilled into the lower conjunctival sac of the affected eye, four times daily up to once per hour.

Duration of treatment

The duration of treatment depends on the type and severity of the disease and is determined by the ophthalmologist. The treatment may extend over a period of several weeks to several years and should be regularly reassessed by an ophthalmologist.

Paediatric population

Serum autolog LUKS, eye drops are not approved for use in the paediatric population.

Methode of administration

Before use, patients should be informed that:
- The eye-drop bottle must be thawed slowly at +2–8 °C (overnight in the refrigerator).
- Hands must be washed thoroughly and dried well.
- Their personal information (name, first name, date of birth) on the label attached to the eye-drop bottle must be checked for accuracy. If the information is not correct, the *Serum autolog LUKS, eye drops* must not be used.

During use, patients should be made aware of the following:
- They must avoid any contact between the tip of the eye-drop bottle and the eye or the surrounding structures in order to reduce the risk of microbial contamination.
- The tip of the eye-drop bottle must not come into contact with any body parts or objects to prevent contamination.
- Improper handling of *Serum autolog LUKS, eye drops* may lead to bacterial contamination, which can cause eye infections. Using contaminated eye drops may result in severe eye damage or even loss of vision.

Patients should also be informed that:
- The eye-drop bottle must be tightly closed immediately after use and stored in the refrigerator at +2–8 °C.
- The eye-drop bottle must not be used for longer than 28 days after thawing.

Contraindications

Serum autolog LUKS, eye drops are contraindicated in patients in the following cases:
- Severe or untreated anaemia.
- Syphilis, hepatitis B, hepatitis C, or HIV infection.
- Infectious conjunctivitis or infectious keratitis.
- Patients with a known history of contact hypersensitivity to silver should not use this product, as the dispensed drops may contain traces of silver released from the container.
- Hypersensitivity to the active substance or excipients.

Warnings and precautions

Serum autolog LUKS, eye drops may only be used by the individual from whom the blood was drawn. Under no circumstances may they be used by a third person. Use by another individual could result in the transmission of infectious diseases.
If *Serum autolog LUKS, eye drops* are administered by a third person, this person must wear gloves to ensure their own personal protection.
The accuracy of the personal information (name, first name, date of birth of the patient) stated on the label of the eye-drop bottle must be checked before each administration.
When using one or more additional ophthalmic treatments, an interval of at least 15 minutes must be maintained between administering different products.
If any 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 the treatment should be considered.

Interactions

At present, no clinically relevant interactions are known. However, since no clinical interaction studies have been conducted so far, it is recommended to maintain an interval of at least 15 minutes between the administration of two products when using one or more other ophthalmic treatments.

Contact lens wearers

Although *Serum autolog LUKS, eye drops* do not contain any preservatives, there are no reliable data regarding their use in contact lens wearers. Therefore, the administration of *Serum autolog LUKS, eye drops* is not recommended while wearing contact lenses.

Pregnancy, lactation

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

Effects on ability to drive and use machines

No corresponding studies have been conducted. *Serum autolog LUKS, eye drops* have a minor influence on the ability to drive or operate machinery. Immediately after applying *Serum autolog LUKS, eye drops*, temporary blurred vision may occur until the drops are distributed across the eye. This should be taken into account when operating machinery and in road traffic. The impairment normally disappears a few minutes after the application of *Serum autolog LUKS, eye drops*. As long as vision has not returned to normal after use, the above-mentioned activities must be avoided.

Undesirable effects

Adverse reactions are arranged according to the MedDRA system organ classes and by 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),
“unknown” (frequency 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 occur. These effects are temporary and have no long-term consequences.
Rare: The following adverse reactions have been reported in clinical studies: 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 the literature, the therapeutic effect of autologous serum eye drops in severe disorders of the ocular surface is based on the epitheliotrophic activity of various substances that occur in different concentrations in serum and in the tear film of a healthy eye. These substances promote, among other things, epithelial proliferation, differentiation, and migration. They include 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.

In addition to biochemical properties resembling those of physiological tear fluid, autologous serum eye drops also contain components that contribute to wound healing. Fibronectin, which is present in serum at levels 10 to 15 times higher than in tear fluid, plays an essential role in the adhesion of epithelial layers to the cornea and is involved in the wound-healing process.

Pharmacodynamics

See “Mechanism of action”.

Clinical efficacy

No clinical studies have been conducted with *Serum autolog LUKS, eye drops*.
Several systematic literature searches, meta-analyses, and a Cochrane review on the efficacy and safety of autologous serum eye drops for the treatment of dry eye (dry eye syndrome, sicca syndrome) have been published.
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 at a concentration of 20% were compared with artificial tears or saline solution in patients with dry eye syndrome of various origins (including associated with Sjögren’s syndrome and after laser surgery). This Cochrane review suggested a temporary short-term relief of symptoms over approximately two weeks during treatment with serum eye drops compared with artificial tears. However, the review found no evidence of an effect after a two-week treatment period.
Other published studies with lower levels of evidence have investigated the long-term use of serum eye drops and suggest potential efficacy with prolonged treatment, although patient-relevant long-term benefits have not been clearly demonstrated.
Robust evidence for long-term efficacy is lacking, and effects on quality of life have not been studied.
LUKS Spitalbetriebe AG uses a concentration different from the 20% autologous serum eye drops evaluated in the Cochrane review.
Although there appears to be no consensus among experts on 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 exploratory only and do not clearly demonstrate equivalence or superiority of higher serum concentrations compared with 20% autologous serum eye drops.

Pharmacokinetics

Absorption

To date, no data are available on the absorption of *Serum autolog LUKS, eye drops.*

Distribution

To date, no data are available on the distribution of *Serum autolog LUKS, eye drops.*

Metabolism

To date, no data are available on the metabolism of *Serum autolog LUKS, eye drops*.

Elimination

To date, no data are available on the elimination of *Serum autolog LUKS, eye drops.*

Kinetics in specific patient groups

To date, no data are available on the kinetics in special patient populations for *Serum autolog LUKS, eye drops.*

Preclinical data

No preclinical safety studies have been conducted in animals.

Other information

Incompatibilities

As no compatibility studies have been performed, this medicinal product must not be mixed with other medicinal products.

Effects on diagnostic methods

To date, no data are available on the influence of *Serum autolog LUKS, eye drops* on diagnostic methods.

Shelf life

The medicinal product may only be used until the date indicated on the packaging as “EXP”.

Shelf life after opening (thawing)

After thawing, the product is stable for 28 days when stored 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 the reach of children.

Instructions for handling

The eye-drop bottle must be thawed slowly at 2–8 °C before use (overnight in the refrigerator).
To maintain sterility, do not touch the dropper tip with the hands or the eye.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Authorisation number

68578 (Swissmedic)

Packs

Serum autolog LUKS 100%, eye drops: 5 ml eye-drop bottle [B]
Serum autolog LUKS 50%, eye drops: 5 ml eye-drop bottle [B]:
The pack size depends on the volume of blood collected.

Marketing authorisation holder

LUKS Spitalbetriebe AG, Luzern

Date of revision of the text

February 2026