

Read this leaflet carefully before you start using **OptiSerum**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please contact your doctor.
- **OptiSerum** Eye Drops has been prescribed to you personally and you should not share your drops with other people. It may harm them, even if their symptoms are the same as yours.

DESCRIPTION:

OptiSerum is an eye drop produced from umbilical cord blood serum which is used to accelerate the healing of wounds on the surface of the eye.

Umbilical cord blood is collected from the umbilical vein immediately after delivery of the baby. The serum is extracted from the blood in the laboratory under sterile conditions, filtered and packaged using aseptic technique. Cord blood serum is not pooled; each donor's serum is batched separately and labelled accordingly.

OptiSerum is intended for allogeneic use. The extracted serum contains natural growth factors and cytokines that, when applied to the ophthalmic surface, promotes and enhances wound healing.

The methods used by Next Biosciences during processing and preservation of the serum are aimed at retaining the cytokines and growth factors.

INDICATIONS:

- Severe dry eye with or without primary Sjögren's syndrome
- Ocular Graft-Versus-Host-Disease (GVHD)
- Persistent epithelial defects
- Recurrent corneal erosions
- Chemical burns
- Neurotrophic keratitis
- Post LASEK surgery
- Post corneal transplant

USAGE INSTRUCTIONS:

OptiSerum is ready to use and no reconstitution of the product is necessary. The eye drops are intended for single patient use only.

When opened, the eye drops must be kept at 4 – 10°C and used within 7 days.

TO THAW THE DROPS:

Remove the **OptiSerum** bottle from freezer and allow to thaw at room temperature. Once thawed, immediately place the bottle in the refrigerator. Do not thaw in microwave or boiling water.

Apply 1-2 drops in the affected eye/eyes, 4 times a day or as otherwise prescribed. Your doctor will tell you how long your treatment will last.

To avoid contamination of your eye drops, do not let the bottle tip touch your eye or any surface. Always wash your hands before applying eye drops. Apply to your eye in the following way:

1. Tilt your head back and look at the ceiling. Hold the bottle with the tip down over your eye.
2. Gently pull the lower eyelid down, until there is a



small pocket between the eyelid and the eyeball.

3. Squeeze the dropper bottle to release a drop into your eye.
4. Replace and tighten the cap immediately after use and place the bottle back in the fridge at 4 - 10°C.

COMPOSITION:

OptiSerum contains:

- Umbilical Cord Blood Serum diluted to 0.2ml serum/ ml of BSS Sterile Irrigation Solution
- BSS Sterile Irrigation Solution is a sterile balanced salt solution, each ml containing:
 - 0.0410% calcium chloride dehydrate (CaCl2·2H2O)
 - 0.03% magnesium chloride hexahydrate (MgCl2·6H2O)
 - 0.39% sodium acetate trihydrate (C2H3NaO2·3H2O)
 - 0.64% sodium chloride (NaCl)

- 0.075% potassium chloride (KCl)
- 0.17% sodium citrate dehydrate (C6H5Na3O7·2H2O)
- sodium hydroxide / hydrogen chloride to adjust pH and water for injection

BIOLOGICAL ACTION:

OptiSerum is a lubricating eye drop produced from umbilical cord serum and BSS Sterile Irrigation Solution. Umbilical cord blood serum contains growth factors which are beneficial to the healing of persistent corneal epithelial defects. These factors include:

- epidermal growth factor (EGF)
- acidic and basic fibroblast growth factor (FGF)
- platelet derived growth factor (PDGF)
- hepatocyte growth factor (HGF)
- vitamin A
- transforming growth factor beta (TGF-β)
- substance P
- insulin-like growth factor (IGF-1)
- nerve growth factor (NGF)
- fibronectin (FN) and
- serum anti-proteases such as α-macroglobulin

CONTRA-INDICATIONS:

- Hypersensitivity to any of the ingredients listed in the composition of **OptiSerum**
- Do not use in case of corneal perforation

STORAGE INSTRUCTIONS:

OptiSerum Eye Drops can be stored as follows until time of use:

Location	Storage Temperature	Shelf Life
Ultra low temperature freezer	-80.0°C	12 Months from date of manufacture
Home freezer	-20.0°C	Within the expiration date printed on the package label
Home refrigerator	4.0 – 10.0°C	Use within 7 days of opening/thawing

WARNINGS:

GENERAL:

- Contains human biological proteins and components
- Keep out of reach of children
- Not tested for endotoxins
- Not tested on animals
- Do not use after the stated expiry date
- For single patient use
- If eye pain, changes in vision or continued redness or irritation of the eye is experienced, or if the condition worsens or persists, discontinue use and consult your doctor

PACKAGING:

- If the bottle is damaged during transportation, please contact Next Biosciences immediately
- Keep the container tightly closed
- Do not use if the tamper-proof seal on the bottle neck is broken before first application
- **OptiSerum** is transported with dry ice to maintain the required temperature: Adhere to dry ice precautions

USE:

- Do not thaw in microwave or boiling water
- Always wash your hands before applying eye drops
- Do not use if product appears cloudy
- Store in original packaging
- Do not let the bottle tip touch your eye or any other surface
- Allow 2-5 minutes after use for product absorption

DRIVING AND USING MACHINERY:

- Do not operate any tools or machines immediately after use
- Do not drive immediately after use as the drops could impair vision

USING OTHER MEDICINES WITH OPTISERUM:

- Concomitant ocular medication should be administered 5 minutes prior to the application of **OptiSerum** to avoid washout effects

IF YOU USE MORE THAN YOU SHOULD:

- It will not cause you any harm. If you are worried, talk to your doctor

PREGNANCY AND LACTATION:

- There is no data on the use of **OptiSerum** during pregnancy and lactation in humans. **OptiSerum** is not expected to be absorbed systemically and therefore will not be excreted in human breast milk.

IDENTIFICATION:

OptiSerum appears as a sterile solution supplied in transparent plastic eye dropper bottles with a ratchet cap, containing 3ml or 4.5ml of solution. Clear, light to dark yellow solution, free from particulate matter. The colour of the solution may range from yellow to light red.

Sizes	Units:	Catalogue #
4.5ml	1	UCS4.5ML
3ml	1	UCS3.0ML
4.5ml	4	UCS4.5ML
3ml	4	UCS3.0ML

CORD BLOOD COLLECTION AND DISEASE TESTING:

OptiSerum is processed from umbilical cord blood, which is recovered aseptically during childbirth from donors who have given informed consent. All donors are screened for infectious, malignant, neurological, and autoimmune diseases to determine whether they are suitable for donation. The donor blood is tested by an independent certified laboratory at the time of delivery.

Only donor blood of donors that have tested negative for the minimum serological tests, including HIV PCR Qualitative, HIV I & II ELISA, Hepatitis B surface antigen (HBsAg), Hepatitis B surface antibodies (HBsAb), Hepatitis B core antibody (HBcAb), Hepatitis C Antibody (HCVAb), HTLV I & II antibodies, Treponema pallidum IgG and IgM, CMV IgG and IgM are used for cord blood serum production.

MICROBIOLOGICAL TESTING:

Random samples of each batch of processed cord blood serum are tested for any signs of growth of aerobic, anaerobic or fungal organisms. The final product is only released after the microbiological testing results yields no growth of micro-organisms.

ADVERSE REACTIONS:

Topical administration of **OptiSerum** does not cause known adverse reactions on the eye, according to previous research, because the components of serum include growth factors and tear components, rather than umbilical cord tissue-derived cells, which may result in increased immunogenicity. In addition, because **OptiSerum** contains no preservatives, this therapy can avoid the risk of toxic reactions on the ocular surface. However, there have been reports of a burning sensation and jelly-like precipitate forming upon initial application.

It is recommended that any adverse reactions occurring due to the use of **OptiSerum** must be reported to the Next Biosciences as soon as possible. An Adverse Event Form will be provided to the doctor, to facilitate an in-depth probe into the cause of the adverse reaction. As **OptiSerum** is a product made from cord blood, during the processing, there may be some haemoglobin left behind which gives the solution a light red colouring. Haemoglobin is an inert molecule and will not cause any adverse reactions.

WARRANTY:

Next Biosciences supplies this product without any express or implied warranties. All statements or descriptions are informational and not given as warranty of the eye drops. Next Biosciences make no guarantee whatsoever to the biological or biomechanical properties of the product. The prescribing ophthalmologist shall be solely responsible for determining the adequacy and appropriateness of the product for any and all uses to which the patient shall apply the product.

Manufactured by: Next Biosciences (Pty) Ltd

Tel: +27 (0)11 697 2900
Web: www.nextbio.co.za
E-Mail: orders@nextbio.co.za
Address: International Business Gateway
Cnr. New Road and 6th Road, Midrand, 1685