

Instructions for use

Please read this carefully as it will help you to use HYLO-FRESH® correctly.

HYLO-FRESH®

Sodium hyaluronate 0.03 %

For relief of irritated eyes.

PRODUCT DESCRIPTION

HYLO-FRESH® are aqueous, sterile, preservative-free, phosphate-free eye drops.

COMPOSITION

1 ml HYLO-FRESH® contains 0.3 mg sodium hyaluronate, Euphrasia-original mother tincture, boric acid, borax and water for injections.

INTENDED PURPOSE

For relief of irritated eyes.

MEDICAL INDICATION

Dry eye disease

SUITABLE FOR

Can be used by adults and children. Please see special dosage recommended in section "Dosage" below.

Another person may assist in the application of the product if the patient is a child, an elderly person or a person who is unable to use the product themselves (e.g., due to injury, illness or limited mobility).

Based on current knowledge, the product can be used during pregnancy or lactation. Please consult your eye doctor before use and see special dosage recommended in section "Dosage" below if you are pregnant or breastfeeding.

Can be used while wearing hard or soft contact lenses.

CLINICAL BENEFIT, PERFORMANCE AND EFFECTIVENESS

Adverse environmental conditions like a dry climate, air conditioning, draughts, air pollution and sunlight, as well as prolonged screen time, for example from watching television or working on a computer or wearing contact lenses can irritate the eyes. This can lead to symptoms such as redness, burning, itching, dryness, tired eyes or foreign body sensation, swelling of the lids or excessive tearing.

HYLO-FRESH® contains sodium hyaluronate and eyebright (*Euphrasia officinalis*), two natural substances. Sodium hyaluronate forms a stable, long-lasting lubricating film on the surface of the eye. Euphrasia has been used in traditional medicine to treat eye irritations.

HYLO-FRESH® moisturizes the eye surface and helps to soothe and relieve irritated and dry eyes in children and adults. HYLO-FRESH® also refreshes the eyes of people who wear contact lenses.

CONTRAINDICATIONS

Do not use if you are hypersensitive to any of the ingredients.

SIDE EFFECTS

The product is preservative free and well tolerated even after prolonged use. In very rare cases, adverse reactions like hypersensitivity, burning or excessive tearing, pain, foreign body sensation or other transient local irritation have been reported which resolved when the product was discontinued.

Temporary blurred vision may occur immediately after application of the solution.

If any serious incident occurs during or as a result of the use of this product, please contact the manufacturer () and your competent authority.

PRECAUTIONS AND WARNINGS

If your symptoms persist or get worse after more than a week of using the product, consult your eye doctor, pharmacist or contact lens specialist.

Take care when using HYLO-FRESH® simultaneously with other eye drops. Apply eye drops first and wait at least 30 minutes before using HYLO-FRESH®.

HYLO-FRESH® should be used last.

Eye ointments should, however, always be administered after using HYLO-FRESH®. Wait at least 30 minutes between applications.

If you are wearing contact lenses, wait approximately 30 minutes after inserting the lenses before using HYLO-FRESH® to avoid any possible incompatibility reactions due to interaction between your contact lens care solution and HYLO-FRESH®.

HYLO-FRESH® contains boric acid and sodium borate in small amounts that are safe if the product is used correctly according to the instructions for use.

One bottle should only be used by a single person ().

DOSAGE

Use the product as needed, depending on the severity of your individual symptoms. Generally, apply one drop in each eye three times a day. If you need to use the product more frequently (e.g. more than 10 times a day), or if your symptoms persist for more than a week or get worse, see your eye doctor or pharmacist.

In infants and young children (under two years old) the product can be used up to three times a day in each eye, and in children over two years old, up to five times a day in each eye.

During pregnancy and lactation HYLO-FRESH® should not be used more than 5 times per day in each eye, because it contains borate buffer.

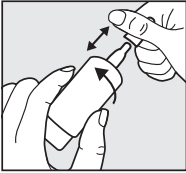
Suitable for long-term use.

GENERAL INSTRUCTIONS FOR USE

Do not use the product if any part of the seal on the folding carton is broken or damaged before first use (☹).

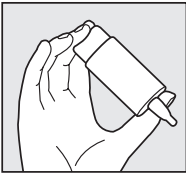
The product is filled in a special COMOD® bottle, a multi-dose container with an airless pump designed to keep the eye drops sterile without using preservatives.

The handling is shown in the following:

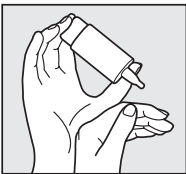


Step 1:
Remove the cap before each use. For this purpose, hold the cap that protects the dropper tip right above the bottle. With your other hand, twist the bottle away from the cap.

Note: Before the first application, the pump mechanism must be activated. Turn the bottle upside down and press repeatedly on the bottom of the bottle until the first drop appears at the dropper tip. The bottle is now ready for further use.



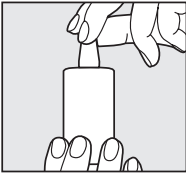
Step 2:
Hold the bottle upside down with the thumb on the shoulder of the bottle and the other fingers on the bottom of the bottle.



Step 3:
Support the hand holding the COMOD® bottle with the other hand.



Step 4:
When applying the eye drops, avoid any contact between the dropper tip and your eye or skin. Tilt your head back slightly and gently pull down your lower eyelid with your free hand. Press firmly and quickly on the bottom of the bottle. This activates the release mechanism to dispense a single drop. Due to the special COMOD® valve system, the size and speed of each drop remain constant regardless of the pressure applied to the bottom of the bottle. Close your eyes after application so that the solution is evenly distributed over the eye surface.



Step 5:
Always ensure that the dropper tip is dry and replace the cap immediately after use. This prevents residual liquid from crystallizing and contaminating the dropper tip.

Contact the manufacturer (🏢), your pharmacist, eye doctor or contact lens specialist if you have any questions about the correct use of this medical device.

10 ml of solution correspond to approximately 300 drops. For technical reasons, a small amount of liquid will remain in the bottle at the end of use.

STORAGE

Do not store above 25 °C (⚡ 25 °C).

The product can be used for 6 months after first opening. Do not use after the expiry date (📅).

Keep the product out of the sight and reach of children.

Dispose of this medical device with your household waste in accordance with local regulations. This will help to protect the environment.

THE FOLLOWING PACK SIZES ARE AVAILABLE

10 ml of eye drops
7.5 ml of eye drops (sample pack)

DATE OF INFORMATION

October 2025

🏢 URSAPHARM Arzneimittel GmbH
Industriestraße 35, 66129 Saarbrücken, Germany
www.ursapharm.de

📦 **UK Responsible Person:**
Scope Ophthalmics Ltd.
1st Floor, Unit 4 Amberley Court
Whitworth Road, County Oak Way
Crawley, West Sussex, RH11 7XL
Freephone: 0808 175 3200
Fax: +44 203 515 9461
Email: info@scopeeyecare.com
www.scopeeyecare.com

CE 0197 MD STERILE A

Symbol	Explanation
📦	Distributor
MD	Medical device
CE	CE mark
UDI	Unique Device Identifier
STERILE A	Sterilized using aseptic processing techniques
LOT	Lot number
📅	Date of manufacture [YYYY-MM]
📖 i	Consult instructions for use
⚠	Contains hazardous substances