Instructions for use for HYLO-TEAR ®

HYLO-TEAR ®

Preservative Free and Phosphate Free

What is HYLO-TEAR ®?

HYLO-TEAR ® is a sterile, phosphate and preservative-free solution for ocular use.

Composition:

1 ml HYLO-TEAR ® contains 1 mg sodium hyaluronate, citric acid anhydrous, sodium citrate, sorbitol and water for injections.

What is HYLO-TEAR ® used for?

To lubricate dry, itchy, burning eyes caused by environmental conditions, injury to the eye or eye surgery.

When should HYLO-TEAR ® be used?

If your eyes are tired, itchy or burning. These sensations may be caused by a lack of moisture on the surface of the eyes brought about, for example, by spending extended periods of time in an air-conditioned room or by using digital devices for an extended period of time. This can lead to break up of the natural tear film on the surface of the eye. HYLO-TEAR ® aims to restore the tear film returning it back to its normal function.

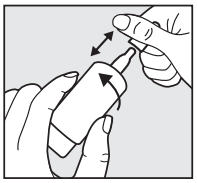
The eyes natural tear film can also be disrupted after surgical intervention or upon injury to the eye. To support the healing process, lubrication is necessary. HYLO-TEAR ® offers long lasting lubrication which supports the natural healing process.

HYLO-TEAR ® contains hyaluronic acid, a natural substance found in both the eyes and elsewhere in the body. Due to its special physical properties, it forms regular, stable, long lasting lubrication. These properties also allow HYLO-TEAR ® to deliver long lasting comfort for contact lens wearers.

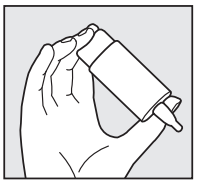
HYLO-TEAR ® is preservative-free and phosphate-free and as a result is very well tolerated.

How should HYLO-TEAR ® be applied?

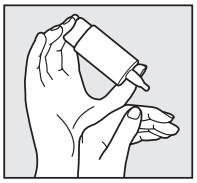
Please do not use HYLO-TEAR ® if any part of the protective seal on the folding carton is broken or damaged before using for the first time ( ).



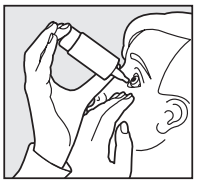
Priming the system:
To prime the system remove the over cap **(see Picture 1)** and invert the HYLO-TEAR ® bottle with its tip pointing down.



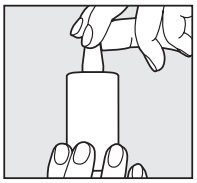
Place two fingers on the base and your thumb on the shoulder of the bottle **(see Picture 2)** and press firmly on the base and release. Repeat this several times until the first drop is released. The bottle is now primed.



General use:
Remove the over-cap and invert the HYLO-TEAR ® bottle with its tip pointing down.
Support the hand holding the bottle with the other hand **(see picture 3)**.



When applying eye drops please avoid any contact between the tip of the bottle and your eye and surrounding skin.
Hold the bottle as previously shown **(see Picture 2).** With your head leaning back slightly, pull down your lower eyelid. Press the base of the bottle. This enables the bottle to release one drop into the conjunctival sac. Release and repeat for the other eye. After each application slowly close your eye to allow the fluid to spread evenly over the eye surface.



The design of the COMOD ® valve system ensures that the size and speed of each drop are the same regardless of the pressure applied to the base of the bottle.

During use please avoid any contact between the tip of the bottle and your eye or your skin.

After application ensure that the tip is dry. Then replace the over-cap back on the bottle **(see Picture 5).**

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HYLO-TEAR® releases 225 equally sized drops of solution (approximately 7.5 ml). A small amount will always remain in the bottle at the end of its life. This is normal.

HYLO-TEAR® can be used for 6 months after opening. The bottle must be discarded after 6 months use. Do not let other people use your HYLO-TEAR®.

Please contact the manufacturer in case of any questions about correct use of this medical device.

What else do you need to know?

If symptoms persist or worsen, consult your Eye Specialist or doctor.
If you use any other eye drop medication, please allow at least 30 minutes after their application before applying HYLO-TEAR®. **Eye ointments** should, however, always be administered **after** using HYLO-TEAR®.

As HYLO-TEAR® is preservative and phosphate-free, it is well tolerated, even when used over extended periods of time. In very rare cases, adverse reactions like hypersensitivity, burning or excessive tearing, pain, foreign body sensation or other temporary local irritations have been reported which ceased once the use of HYLO-TEAR® was discontinued.
If your symptoms do not improve upon cessation, then please contact your Eye Specialist or doctor immediately.

Please note that temporary blurred vision is possible after application of HYLO-TEAR® due to its viscosity. In very rare cases, this may cause temporary headache in sensitive patients.

For Contact lens wearers, we recommend waiting 30 minutes after you have inserted your contact lens for best results and comfort.

According to existing knowledge HYLO-TEAR® can be used in children, pregnant and breast-feeding women.

In the event of a serious incident occurring during the use of this medical device or as a result of its use, please report the incidence to the manufacturer ( ).

How often and for how long can you use HYLO-TEAR®?

Normally one drop of HYLO-TEAR® three times a day can be instilled into each eye. If you use HYLO-TEAR® more frequently or if your symptoms persist or worsen for more than one week after first use, please consult your Eye Specialist or doctor.

When should you not use HYLO-TEAR®?

HYLO-TEAR® should not be used if you are sensitive to any of the ingredients.

What you need to know about storing HYLO-TEAR®?

Do not store above 25 °C (25 °C).

HYLO-TEAR® must be discarded 6 months after opening. To help you remember the container label has a space where you can note the date that the product is first used.

Do not use beyond expiry date ( ).

Keep out of the reach of children.

HYLO-TEAR® is compatible with contact lenses.

Dispose of this medical device via household waste according to your national legislation. This measure will help to protect the environment.

Date of revision of the text:

May 2023

Manufacturer ( ):

URSAPHARM Arzneimittel GmbH, Industriestraße, 66129 Saarbrücken, Germany

Distributor ( ) :

Scope Ophthalmics Ltd,
Suite 5,
Westland House
Willow Road
Dublin 12, Ireland
Freephone 1800 816 005
www.scopeeyecare.com

The following pack sizes are available:

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

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Medical Device

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