

Instructions for use

Please read this information carefully because it will help you to use HYLO-TEAR® properly.

HYLO-TEAR®

Sodium hyaluronate 0.1 %

To improve the lubrication of the eye surface in eyes that are dry, burning or have foreign body sensations due to environmental conditions as well as after ophtho-mo-surgical interventions.

Sterile, phosphate-free eye drops without preservatives

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 improve the lubrication of the eye surface in eyes that are dry, burning or have foreign body sensations due to environmental conditions as well as after ophtho-mo-surgical interventions.

When should HYLO-TEAR® be used?

If your eyes are itching, burning or easily tiring, if it feels as if you had sand in your eyes, this might be due to a lack of moisture on the surface of your eyes. If you spent a longer time in an air-conditioned room, for example, or after intense computer work the natural tear film that usually covers the eye surface breaks up more quickly. For your eye tissue to be fully functioning, it needs to be continuously lubricated by a tear film.

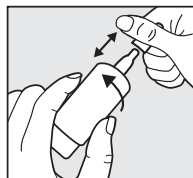
Due to surgical interventions on the eye or after injuries of the eye the physiologic secretion of tears can be reduced. However, for the regeneration of the superficial tissues of the eye a continuous and sufficient lubrication is necessary. The application of HYLO-TEAR® supplies long lasting moisture to cornea and conjunctiva so that the physiologic process of healing is efficaciously supported.

HYLO-TEAR® contains the sodium salt or the 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 lubricating moisture film on the ocular surface that is not easily rinsed off. It does, however, not cause blurred vision and protects your eyes from dryness and irritation for a long time. This is particularly important if you wear contact lenses because the contact lens needs to swim in sufficient tear fluid in order not to cause any discomfort. HYLO-TEAR® may be used while wearing contact lenses. Wearing contact lenses will be made more comfortable by using HYLO-TEAR® as it does not form crusts or deposits.

As HYLO-TEAR® is preservative-free it is usually very well tolerated. Additionally, HYLO-TEAR® is free of phosphates so that complications like deposits in the cornea are avoided.

How should HYLO-TEAR® be applied?

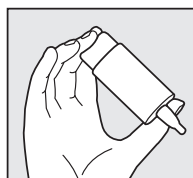
Please do not use HYLO-TEAR® if any part of the protective seal on the folding carton is broken or damaged before using for the first time (☉).



Step 1:

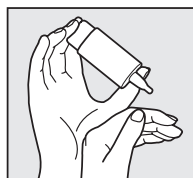
Remove cap before use.

To do this, hold the cap above the bottle. With your other hand, pull away the bottle from the cap with a rotary movement. Before the first application please turn the HYLO-TEAR® bottle with its tip down and press the bottom of the bottle repeatedly until the first drop appears at the nozzle. Now the bottle is ready for further use.



Step 2:

Hold the bottle upside down and place your thumb on the shoulder of the bottle and the other fingers on the base of the bottle.



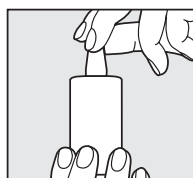
Step 3:

Support the hand holding the COMOD®-bottle with your other hand as shown.



Step 4:

During use, please avoid any contact between the tip of the bottle and your eye or your skin. With your head leaning back slightly, gently pull down your lower eyelid. Press the base of the bottle vigorously and quickly. This activates the mechanism to release one drop. Because of the special COMOD® valve system, size and speed of each drop remain constant regardless of the pressure applied to the base of the bottle. Slowly close your eyes to allow the fluid to spread evenly on the eye surface.



Step 5:

Replace cap immediately and carefully after use. Ensure that the dropper tip is dry.

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

A bottle containing 10 ml so solution corresponds to approximately 300 drops. For technical reasons a small amount will remain in the bottle.

HYLO-TEAR® can be used for an unlimited period of time. HYLO-TEAR® eye drops are only for you, even people with similar symptoms should not use your eye drops ().

What else do you need to know?

If you do not feel better or if you feel worse after several days of use talk to your doctor or pharmacist.

If you use any other eye drop, there should be at least 30 minutes between the applications, and HYLO-TEAR® should always be used last. **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.

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.

HYLO-TEAR® may be used while wearing contact lenses. After inserting contact lenses, waiting for about 30 minutes before applying the eye drops is recommended. In doing so you avoid intolerance reactions which may occur due to interactions between lens care products and HYLO-TEAR®. 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 hypersensitive to one of the ingredients.

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

Do not store above 25 °C ( 25 °C).

HYLO-TEAR® can be used for 6 months after opening.

Do not use beyond expiry date ().

Keep out of the reach of children.

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

The following package sizes are available:

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

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August 2024

Manufacturer ():

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66129 Saarbrücken
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and UK Responsible Person:

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Symbol:	Explanation:
	Manufacturer
	Distributor
	Medical device
	CE mark
	Sterilized using aseptic processing techniques
	Do not use if the outer packaging is damaged.
	Lot number
	Expiry date [YYYY-MM]
	Read Instructions for use
 25 °C	Do not store above 25°C.
	Single patient multiple use

