

Instructions for use

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

HYLO-DUAL®

Sodium hyaluronate and ectoin

Moisturizes dry eyes, stabilizes the tear film and relieves inflammatory and allergic symptoms such as itching and burning.

What is HYLO-DUAL®?

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

Composition:

1 ml of HYLO-DUAL® contains 0.5 mg sodium hyaluronate, 20 mg ectoin, boric acid, borax and water for injections.

What is HYLO-DUAL® used for?

HYLO-DUAL® moisturizes the cornea and conjunctiva and protects against excessive evaporation of tears. This stabilisation of tears relieves the inflammatory symptoms of irritated eyes. In addition, it also relieves the itching and burning sensations associated with allergy.

When should HYLO-DUAL® be used?

HYLO-DUAL® is indicated for the treatment of dry eye disease.

Burning, itching, tearing, foreign body sensation or the sensation of dry eyes are symptoms of an irritated eye. Quite often this is a result of insufficient lubrication of the surface of the eye. Other symptoms can be triggered by hypersensitivities against certain substances (e.g. pollen, animal hair or house dust). As an allergy shows similar symptoms, it is difficult to differentiate between a dry or an allergic eye.

In these cases, the dual mode of action of sodium hyaluronate and ectoin in HYLO-DUAL® helps to relieve these symptoms.

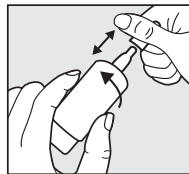
HYLO-DUAL® contains sodium hyaluronate, a physiologic substance which is found in the eye but also in other tissues of the body. Sodium hyaluronate provides an even, stable, especially long lasting lubrication to the surface of the eye without being rinsed away quickly.

Ectoin is a natural substance gained from microorganisms that live in an extreme environment (e. g. salt lakes). To be protected against these extreme environmental conditions, these microorganisms form the natural substance ectoine. Its specific properties are used in HYLO-DUAL®. Ectoin increases the binding of water at the cells of the ocular surface. This forms a physiologic barrier on the conjunctiva against allergenic acting substances. Ectoine stabilizes the lipid layer of the tear film that protects against excessive evaporation of tears.

The interaction of sodium hyaluronate and ectoine provides intensive long lasting lubrication of the ocular surface and protects against evaporation of tears. The typical symptoms of itching and burning that occur as inflammatory reactions to environmentally triggered irritations as well as to allergic reactions are relieved by HYLO-DUAL®.

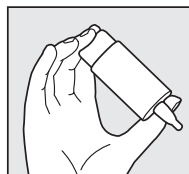
How should HYLO-DUAL® be applied?

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



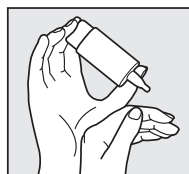
Step 1:

Remove the 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-DUAL® 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.



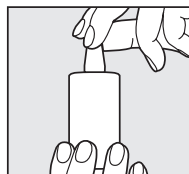
Step 3:

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



Step 4:

When applying the eye drops, please avoid any contact between the tip of the bottle and your eye and skin. With your head leaning back slightly, gently pull down your lower eyelid. Press the base of the bottle quickly. This activates the mechanism to release one drop. Because of the special COMOD® valve system, the 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 surface of the eye.



Step 5:

Replace cap immediately after use. Before doing so, ensure the tip of the bottle is dry.

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

A bottle containing 7.5 ml of solution corresponds to approximately 225 drops. For technical reasons, a small volume of solution will always remains in the bottle. HYLO-DUAL® can be used for an unlimited period of time and can be used by adults and children 6 years and older. Each bottle HYLO-DUAL® should be used only by the same person ().

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 drops, there should be at least 30 minutes between the applications and HYLO-DUAL® should always be used last. **Eye ointments** should, however, always be administered **after** using HYLO-DUAL®.

HYLO-DUAL® is phosphate-free and preservative-free it is well tolerated even when used over an extended period 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 stopwhen the use of HYLO-DUAL® is discontinued.

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

HYLO-DUAL® can be used while wearing contact lenses. After inserting contact lenses, it is recommended to wait about 30 minutes before applying the eye drops. By doing this, you avoid intolerance reactions which may occur due to interactions between lens care products and HYLO-DUAL®.

Based on the available evidence, HYLO-DUAL® may be used in children 6 years and older, and pregnant and breast-feeding women.

In case a serious incident has occurred during the use of this medical device or as a result of its use, please report it to the manufacturer ().

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

Generally, adults and children 6 years and older instil one drop of HYLO-DUAL® **three times a day** into each eye. If you apply HYLO-DUAL® more frequently (e.g. more than 10 times per day) or suffer from more severe complaints you should consult an ophthalmologist in regular intervals. During pregnancy and lactation HYLO-DUAL® should not be used more than 10 times per day, because it contains borate buffer.

HYLO-DUAL® is suitable for long-term treatment. However – as in all persisting symptoms – you should consult your ophthalmologist if your complaints do not improve e. g. within two weeks.

When should you not use HYLO-DUAL®?

HYLO-DUAL® should not be used if you hypersensitive to one of the ingredients and in children younger than 6 years.

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

Do not store above 25°C ( 25 °C).

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

Do not use beyond the expiry date ().

Keep out of the reach of children.

Dispose 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
- 7.5 ml of eye drops (sample pack)

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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

