

## Instructions for use

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

# HYLO DUAL INTENSE®

0.2 % Sodium hyaluronate and 2 % ectoin

For intensive therapeutic lubrication of dry eyes and stabilisation of the tear film.  
Relieves inflammatory symptoms such as itching and burning.

Sterile, phosphate-free and preservative free eye drops.

### What is HYLO DUAL INTENSE®?

HYLO DUAL INTENSE® is a sterile preservative-free solution for ocular use.

### Composition:

HYLO DUAL INTENSE® contains 0.2 % sodium hyaluronate, 2 % ectoin, boric acid, borax and water for injections.

### What is HYLO DUAL INTENSE® used for?

HYLO DUAL INTENSE® is for the intensive therapeutic lubrication of dry eyes and stabilisation of the tear film. Relieves inflammatory symptoms such as itching and burning.

### When should HYLO DUAL INTENSE® be used?

HYLO DUAL INTENSE® is indicated for the treatment of dry eye disease where symptoms of burning, itching, tearing, foreign body sensation or the sensations of severe and persistent dry eyes are present.

In cases, HYLO DUAL INTENSE® is advantageous because of the dual mode of action of sodium hyaluronate and ectoin.

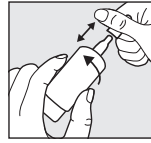
HYLO DUAL INTENSE® contains the sodium salt of hyaluronic acid, a natural substance found in many organs of the human body including the eye. Its particular physical property is that it forms a regular, stable and long lasting, lubricating and moisturising film on the eye surface that is not easily rinsed off. This so-called bioadhesive property ensures that the cornea and conjunctiva are protected, enhancing the effect of the physiologic tears so the eyelid spreads easily over the surface of the eye. HYLO DUAL INTENSE® contains a higher amount of sodium hyaluronate which makes it more viscous. This provides the eye with an intensive, soothing and long-lasting moisturising film. Persistent or more severe symptoms are relieved and the eye is protected against further irritation.

The other component is ectoin. Ectoin is a natural substance formed by microorganisms to protect themselves from extreme environments (e. g. salt lakes). Its specific properties are used in HYLO DUAL INTENSE®. Ectoin increases the binding of water to the cells of the ocular surface to form a physiologic barrier on the conjunctiva. Simultaneously, ectoine stabilizes the lipid layer of the tear film that protects against excessive evaporation of tears.

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

### How should HYLO DUAL INTENSE be applied?

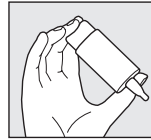
Please do not use HYLO DUAL INTENSE® if the seal on the folding carton is broken or damaged before using for the first time (⊗).



#### Step 1:

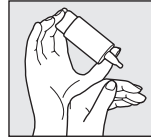
Remove the cap before use.

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 INTENSE® 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.



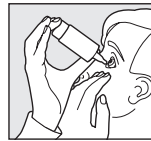
#### Step 2:

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.



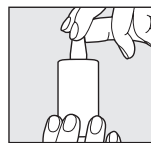
#### Step 3:

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 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 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 of solution corresponds to approximately 300 drops. For technical reasons a small amount will remain in the bottle. This is normal.

HYLO DUAL INTENSE® is suitable for long term treatment and can be used by adults and children 6 years and older.

Each bottle HYLO DUAL INTENSE® should be used only by the same person (♻️).

### What else do you need to know?


If your symptoms persist or worsen 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 INTENSE® should always be used last. Eye ointments should not be administered concomitantly with HYLO DUAL INTENSE®.

As HYLO DUAL INTENSE® is preservative-free it is well tolerated even when used over a long period of time. In very rare cases adverse reactions like hypersensitivity, burning or excessive tearing, pain, foreign body sensation and other temporary local irritations have been reported which stop immediately when the use of HYLO DUAL INTENSE® is discontinued.

Please note that temporary blurred vision is possible after application of HYLO DUAL INTENSE® due to the viscosity of the eye drops solution. In very rare cases this may cause temporary headache in sensitive patients. Due to the high viscosity, HYLO DUAL INTENSE® should not be used while wearing contact lenses.

There are no controlled clinical data about the use of HYLO DUAL INTENSE® in children, or during pregnancy and lactation. Based on existing evidence HYLO DUAL INTENSE® can be used in children older than 6 years, or during pregnancy and lactation.

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 INTENSE®?

Generally, adults and children 6 years and older instil one drop of HYLO DUAL INTENSE® three times a day into the conjunctival sac of each eye. If you apply HYLO DUAL INTENSE® more frequently (e.g., more than 10 times per day) or suffer from more severe complaints you should consult an ophthalmologist regularly.

During pregnancy and lactation as well as in children younger than 12 years HYLO DUAL INTENSE® should not be used more than 10 times per day.

HYLO DUAL INTENSE® is suitable for long-term treatment.

However – as in all persisting symptoms – you should consult your ophthalmologist if your symptoms do not improve e. g. within two weeks.

### When should you not use HYLO DUAL INTENSE®?

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

HYLO DUAL INTENSE® should not be used while wearing contact lenses.

### What you need to know about storing HYLO DUAL INTENSE®?

Do not store above 25 °C (  25 °C ).

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


Do not use beyond 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.

### Date of information:

March 2023

 URSAPHARM Arzneimittel GmbH  
Industriestraße 35  
66129 Saarbrücken  
Germany

### and UK Responsible Person:












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### The following package sizes are available:

10 ml of eye drops

7.5 ml of eye drops (sample pack)



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