

## Instruction for use for HYLO-DUAL®

# HYLO-DUAL®

Sodium hyaluronate's and ectoin's dual mode of action  
lubricates the eye and stabilizes the lipid layer of the tear film.  
Preservative Free and phosphate free, contact lens compatible and  
can be used for 6 months from opening.

### 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?

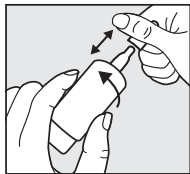
Burning, itching, tearing, foreign body sensation or the sensation of dry eyes are symptoms of an irritated eye. Quite often this is a result of insufficient lubrication of the surface of the eye. Other symptoms can be triggered by allergy, for example, pollen, animal hair or dust. As an allergy shows 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 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 even, stable and long lasting lubrication to the surface of the eye.

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 ectoin. 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. Ectoin 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 of itching and burning that occur as inflammatory reactions to environmentally triggered irritations as well as to allergic reactions are relieved by HYLO-DUAL®.

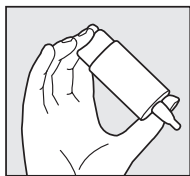
### How should HYLO-DUAL® be applied?

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 (  ).

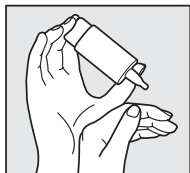


#### Priming the system:

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

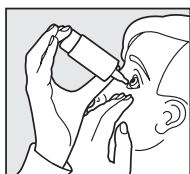


Place two fingers on the base and your thumb on the shoulder of the bottle (**see Picture 2**) and press firmly on the base and release. Repeat this several times until the first drop is released. Now the bottle is primed.

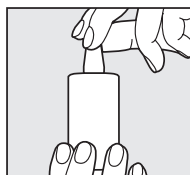


#### General use:

Remove the over-cap and invert the HYLO-DUAL® bottle with its tip pointing down. Support the hand holding the bottle with the other hand (**see Picture 3**).



Hold the bottle as previously shown (**see Picture 4**). 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.

Before replacing the over-cap please ensure that the tip is dry (see Picture 5).

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

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

#### **What else do you need to know?**

If you use any other eye drops please allow at least 30 minutes after the application before applying HYLO-DUAL®.

**Eye ointments** should, however, always be administered **after** using HYLO-DUAL®.

As HYLO-DUAL® is phosphate-free and preservative-free it is well tolerated even when used over extended periods of time. Hypersensitive reactions rarely occur but if you experience burning or excessive tearing please stop using HYLO-DUAL®.

HYLO-DUAL® is compatible with contact lenses. If you are a contact lens wearer and you experience such a reaction, please check to see if there has been any change in your contact lens solution, as this may be the cause of the reaction.

If your symptoms do not disappear then please contact your doctor immediately.

There are no findings about the use of HYLO-DUAL® during pregnancy and lactation. Please ask your doctor or pharmacist before you use HYLO-DUAL® if you are pregnant, could be pregnant or are breast-feeding.

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


HYLO-DUAL® should be used according to the instructions given by your doctor or your eye specialist. Generally adults and children 6 years and older instil one drop of HYLO-DUAL® **three times a day** into each eye. If necessary it can also be used more frequently.

HYLO-DUAL® is suitable for long term treatment. Please consult your doctor or eye specialist if your symptoms persist, begin to deteriorate or HYLO-DUAL® needs to be applied very frequently (e.g. about 10 times a day).


#### **When should you not use HYLO-DUAL®?**

HYLO-DUAL® should not be used if you sensitive to any 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® 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 the expiry date (  ).

Keep out of the reach of children.

#### **Date of revision of the text:**

June 2020

#### **Manufacturer :**

URSAPHARM Arzneimittel GmbH

Industriestraße 35

66129 Saarbrücken

Germany

#### **Distributor:**

SCOPE OPHTHALMICS Ltd.

Suite 4/5,

Westland House,

Willow Road

Dublin 12

Freephone 1800816005

www.scopeeyecare.com

#### **The following package sizes are available:**

7.5 ml of eye drops

7.5 ml of eye drops (sample pack)

 0197

STERILE A

Medical device