

Instructions for use for HYLO-CARE®

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

HYLO-CARE®

sodium hyaluronate 0.1% and dexpanthenol 2%

For lubrication and support of healing of a damaged surface of the eye e.g. due to dry eyes or surgical procedures.

Sterile, phosphate-free eye drops without preservatives.

What is HYLO-CARE®?

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

Composition:

1 ml HYLO-CARE contains 1 mg sodium hyaluronate, 20 mg dexpanthenol, citric acid anhydrous, sodium citrate and water for injections.

What is HYLO-CARE® used for?

For lubrication and support of healing of a damaged surface of the eye e.g. due to dry eyes or surgical procedures.

When should HYLO-CARE® be used?

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

To maintain and regenerate the ocular surface (cornea and conjunctiva) it must be kept continuously moist. Normally our tears fulfil this role. However, in some cases there are not enough tears or their composition is disturbed. In these cases the eye reacts with redness, itching, foreign body, burning sensation, or acute tiredness. These symptoms of an inadequate supply of physiological tears may occur in dry or air-conditioned environments, as well as a result of a medical treatment or purely due to age.

The epithelial cells of the cornea and conjunctiva are continuously restored, and this process works best in a humid environment. Therefore, after surgical procedures it is vital that the ocular surface is sufficiently lubricated to allow proper wound healing.

In all these cases it is advisable to apply intensive humidity to the eye by using HYLO-CARE® in order to renew the physiologic balance of lubrication and moisturisation of the eye.

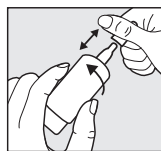
HYLO-CARE® contains the sodium salt of Hyaluronic Acid, a physiological substance of the eye but also of other parts of the body. Sodium hyaluronate has unique properties which allow it to form an even and long-lasting lubricating film on the surface of the eye without being rinsed away quickly. Consequently, the moisturising effect is prolonged without impairing vision. Therefore HYLO-CARE® can be used during the day while eye ointments and gels can cause blurred vision because of their greasy consistency.

Additionally, HYLO-CARE® contains dexpanthenol which belongs to the extensive group of B vitamins. This component assists the eye during its phase of intensive regeneration while the lubricating properties of sodium hyaluronate further support this process. In addition to this, dexpanthenol supports wound healing and so superficial erosions on the ocular surface caused by an insufficient tear film as well as wounds, which are sometimes a result of surgical procedures, can both heal faster.

HYLO-CARE® ensures not only a sufficient supply of humidity to the eye but at the same time enhances the regeneration of corneal and conjunctival epithelia.

How should HYLO-CARE® be applied?

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

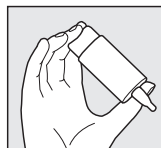


Step 1:

Remove cap before use.

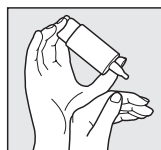
To do this, hold the cap above the bottle. With your other hand, pull away the bottle from the cap with a rotary movement.

Before the first application please turn the HYLO-CARE® 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:

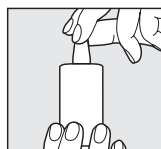
Support the hand holding the COMOD®-bottle with your other hand as shown.



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 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 7.5 ml of solution corresponds to approximately 225 drops.

HYLO CARE is suitable for long term treatment and can be used by adults and children without limitation of age.

HYLO CARE is only for you, even people with similar symptoms should not use your eye drops ().

What else do you need to know?

If 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-CARE® should always be used last. Eye ointments should, however, always be administered after using HYLO-CARE®.

Because it is preservative-free, HYLO-CARE® is well tolerated even when used over a longer 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 subsequently stopped when the use of HYLO-CARE® was discontinued.

HYLO-CARE® 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-CARE®.

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

According to existing knowledge HYLO-CARE® may be used in children or 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-CARE®?

Generally, you instil one drop of HYLO-CARE® three times a day into each eye.

If you use HYLO-CARE® more frequently or when your complaints persist for more than one week, please consult your eye doctor or pharmacist.

When should you not use HYLO-CARE®?

HYLO-CARE® should not be used if you are oversensitive to one of the ingredients.

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

- Do not store above 25 °C ().
- HYLO-CARE® must be discarded 6 months after 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 will help to protect the environment.

The following package sizes are available:

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

Date of information:

March 2024

 **Manufacturer:**
URSAPHARM Arzneimittel GmbH
Industriestraße 35
66129 Saarbrücken
Germany

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

CE0197

MD

STERILEA

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

