

Instructions for use

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

HYLO-FORTE®

Sodium hyaluronate 0.2 %

For the intensive, therapeutic lubrication of the ocular surface in more severe and persistent dry eye sensation as well as after surgical interventions on the eye.

Sterile, phosphate-free solution without preservatives

What is HYLO-FORTE®?

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

Composition:

1 ml HYLO-FORTE® contains 2 mg sodium hyaluronate, citric acid anhydrous, sodium citrate, sorbitol and water for injections.

What is HYLO-FORTE® used for?

HYLO-FORTE® is an eye drop for the intensive, therapeutic lubrication of the ocular surface in more severe and persistent dry eye sensation including treatment after surgical interventions on the eye.

When should HYLO-FORTE® be used?

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

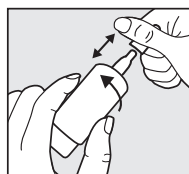
HYLO-FORTE® contains the sodium salt of hyaluronic acid, a natural substance found in many organs of the human body including the eye. Its unique property is that it forms a regular, stable, long lasting, lubricating and moisturising film on the eye surface that is not easily rinsed off. This so-called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

Due to surgical interventions on the eye or after eye injuries the physiologic tear secretion may be reduced. A continuous moisturising of the surface of the eye is necessary for the regeneration of the eye's tissues. By applying HYLO-FORTE®, increased moisture and lubrication is supplied to cornea and conjunctiva so that the physiological wound healing process is optimal.

Being preservative-free HYLO-FORTE® is usually very well tolerated. Additionally, HYLO-FORTE® is free of phosphates so that possible complications due to the formation of insoluble deposits in the cornea are avoided.

How should HYLO-FORTE® be applied?

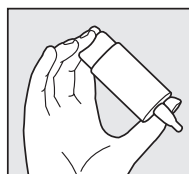
Please do not use HYLO-FORTE® if any part of the protective seal on the folding carton is broken or damaged before using for the first time (☹).



Step 1:

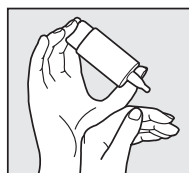
Remove the cap before use.

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-FORTE® 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.



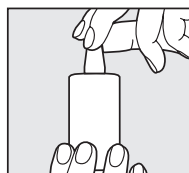
Step 3:

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, 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 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 question 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 always remains in the bottle.

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

Each bottle HYLO-FORTE® should be used only by the same person ().

What else do you need to know?

If you use any other eye drops there should be at least 30 minutes between the applications, and HYLO-FORTE® should always be used last. **Eye ointments** should, however, always be administered **after** using HYLO-FORTE®.

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

As HYLO-FORTE® is preservative-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 stop immediately when the use of HYLO-FORTE® is discontinued. Please note that temporary blurred vision is possible after application of HYLO-FORTE® due to the viscosity of the eye drops solution. In very rare cases this may cause temporary headache in sensitive patients.

HYLO-FORTE® relieves the symptoms in case of more severe or persistent dry eye sensation. HYLO-FORTE® may be used while wearing contact lenses, in consultation with your specialist. However, in these cases, there may be some smearing on the contact lenses that will disappear after blinking a few times.

After inserting contact lenses, waiting for about 30 minutes before applying the eye drops is recommended. In this way, you avoid intolerance reactions which may occur due to interactions between lens care products and HYLO-FORTE®.

Based on available evidence HYLO-FORTE® can be used in children, 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-FORTE®?

Generally, you instil one drop of HYLO-FORTE® three times a day into each eye. If necessary, it can also be used more frequently. If you use HYLO-FORTE® more frequently (e. g. more than 10 times per day) or when your complaints persist, please consult your eye doctor or pharmacist.

When should you not use HYLO-FORTE®?

Do not use HYLO-FORTE® if you are hypersensitive to one of the ingredients.

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

Do not store above 25°C ( 25 °C).

HYLO-FORTE® 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.

The following package sizes are available:

7.5 ml of eye drops (sample)

10 ml of eye drops

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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

