

Instructions for use

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

HYLO-FORTE®

Sodium hyaluronate 2 mg/ml

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

What is HYLO-FORTE®?

HYLO-FORTE® is a sterile, phosphate-free 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 and therapeutic lubrication of the ocular surface in more severe and persistent dry eye disease 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.

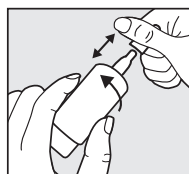
HYLO-FORTE® contains the sodium salt of hyaluronic acid, a natural substance found in many organs of the human body including the eye. Its unique property is that it forms a regular, stable, long lasting, lubricating and moisturising film on the eye surface. This so-called bioadhesive properties ensure 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 concentration 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 tissues. By applying HYLO-FORTE®, supplementary moisturising and lubrication is supplied to the cornea and conjunctiva so that the physiological wound healing process is optimal.

Because HYLO-FORTE® is preservative free, it is usually very well tolerated. Additionally, HYLO-FORTE® does not contain phosphates, so it helps to avoid complications like calcium deposits on the cornea.

How should HYLO-FORTE® be applied?

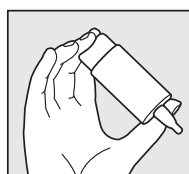
Please do not use HYLO-FORTE® if any of the protective seal on the folding carton is broken or damaged before using the first time (☹).



Step 1:

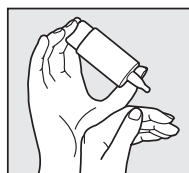
Remove the cap before use.

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.



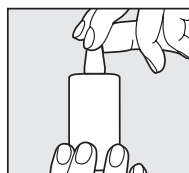
Step 3:

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 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 surface of the eye.



Step 5:

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

Please contact the manufacturer in case of any question 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-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 drop there should be at least 30 minutes between the application, 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.

HYLO-FORTE® is preservative-free it is well tolerated even when used for 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 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 associated with more severe or persistent dry eye disease. HYLO-FORTE® may be used while wearing contact lenses, in consultation with your eye doctor. Some smearing on the contact lenses may occur, but will disappear after blinking a few times.

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 contact 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 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:
October 2022

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Germany

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Freephone 1800 816 005
www.scopeeyecare.ie

The following pack sizes are available:
7.5 ml of eye drops (sample)
7.5 ml of eye drops

 0197





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
	Do not store above 25°C.
	Single patient multiple use

