

Instructions for use for HYLO-FORTE®

HYLO-FORTE®

Preservative Free and Phosphate Free

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 and therapeutic lubrication of the ocular surface in more severe and persistent dry eye sensation including treatment after surgical procedures.

When should HYLO-FORTE® be used?

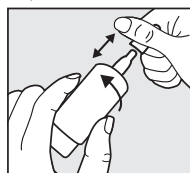
HYLO-FORTE® eye drops are used to intensely lubricate the surface of the eye in more severe or persistent cases of dry eye. HYLO-FORTE® contains the sodium salt of hyaluronic acid, a natural substance found in many organs of the human body including the eye. Its special property is that it forms a regular, stable, long lasting, lubricating and moisturising film on the eye surface that is not easily rinsed off. These bioadhesive properties ensure that the cornea and conjunctiva are protected, and together with the physiological tears, the eye lid slides 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. 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.

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 of the protective seal on the folding carton is broken or damaged before using the first time (☉).

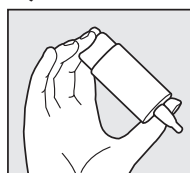
1.)



Priming the system:

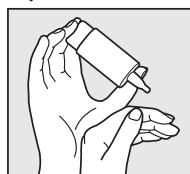
To prime the system remove the over cap (**see picture 1**) and invert the HYLO-FORTE® bottle with its tip pointing down.

2.)



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.

3.)



General use:

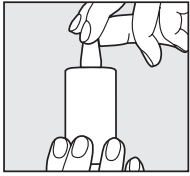
Remove the over-cap and invert the HYLO-FORTE® bottle with its tip pointing down. Support the hand holding the bottle with the other hand (**see picture 3**).

4.)



Hold the bottle as previously shown (**see Picture 2**). 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.

5.)



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-FORTE® releases 225 drops of solution (7.5 ml). After the last drop is released a small amount of solution will remain in the bottle. This is normal.

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

What else do you need to know?

If you use any other eye drop medication please allow at least 30 minutes after the application before applying HYLO-FORTE®. **Eye ointments** should, however, always be administered **after** using HYLO-FORTE®.

As HYLO-FORTE® 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-FORTE®.

Please note that temporary blurred vision can occur after application of HYLO-FORTE® due to the viscosity of the eye drops solution.

HYLO-FORTE® relieves the symptoms of more severe or persistent dry eyes. HYLO-FORTE® may be used while wearing contact lenses, in consultation with your doctor.

HYLO-FORTE® is suitable for use with hard or soft contact lenses. However, there may be some smearing on the contact lenses that will disappear after blinking a few times.

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

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.

HYLO-FORTE® is compatible with contact lenses.

There are no restrictions for the use of HYLO-FORTE® in children or pregnant and breast feeding women.

How often and for how long can you use HYLO-FORTE®?

HYLO-FORTE® should be used according to the instructions given by your doctor or your eye specialist. Normally one drop of HYLO-FORTE® three times a day can be instilled into each eye. If necessary it can also be used more frequently.


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

When should you not use HYLO-FORTE®?


HYLO-FORTE® should not be used if you are sensitive to any of the ingredients.

What you need to know about storing

HYLO-FORTE®?

Do not store above 25°C ( 25°C).

HYLO-FORTE® 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 expiry date ().

Keep out of reach of children.

Date of information:

April 2018

Manufacturer ():

URSAPHARM Arzneimittel GmbH, Industriestraße, 66129 Saarbrücken, Germany

Tel.: +49 6805/9292-0

Fax: +49 6805 / 92 92 -88

Email: info@ursapharm.de

www.ursapharm.de

Distributed by

Scope Ophthalmics Ltd.

Suite 4/5,

Westland House

Willow Road

Dublin 12

Freephone 1800 816 005

www.scopeophthalmics.com

The following pack sizes are available:

7.5 ml of eye drops (sample)

7.5 ml of eye drops

 0197

Medical Device

STERILE A

