

Instructions for Use: HYLO-FORTE® Eye Drops

Sodium hyaluronate 2 mg/mL eye drops

What is in this leaflet

This leaflet answers some common questions about HYLO-FORTE® . It explains how to use HYLO-FORTE® correctly.

It does not contain all available information about HYLO-FORTE® . It does not take the place of talking to your doctor, pharmacist, ophthalmologist or other health professionals.

Keep this leaflet. You may need to read it again.

What the HYLO-FORTE® is used for

HYLO-FORTE® is used to improve lubrication of the eye surface, in eyes that are severely dry, irritated and tired from external factors e.g. prolonged exposure to video screens and monitors, air conditioning, dust, pollution, smoke etc.

Your health professional may also recommend its use after surgical procedures on the eye.

HYLO-FORTE® is a sterile, preservative-free solution containing 2 mg/mL sodium hyaluronate, a citrate buffer, sorbitol and water.

When should HYLO-FORTE® be used

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

If your eyes are persistently itching, burning, or tiring easily, if it feels as if you have grit in your eyes, this may be due to a severe lack of moisture on the eye's surface. If you spend a long time in an air-conditioned room or doing intense computer work, the natural tear film that usually covers the eye surface breaks up quicker. For your eye tissue to be fully functioning it needs to be continuously lubricated by a tear film. The higher viscosity of HYLO-FORTE® provides the eye with an intensive, soothing and longer lasting film.

After surgical procedures or injuries to the eye, tear secretion can be reduced. However, for the regeneration of the superficial tissues of the eye, continuous, adequate lubrication is required. Use of HYLO-FORTE® provides long lasting moisture to the cornea and conjunctiva so that the physiologic healing process is efficaciously supported.

HYLO-FORTE® contains the sodium salt of hyaluronic acid, a natural substance which is found in the eye and other parts of the body. Because of its special physical properties, it forms a natural, stable, long lasting moisture film that is not easily rinsed off, on the ocular surface. It provides long lasting protection from eye dryness and irritation.

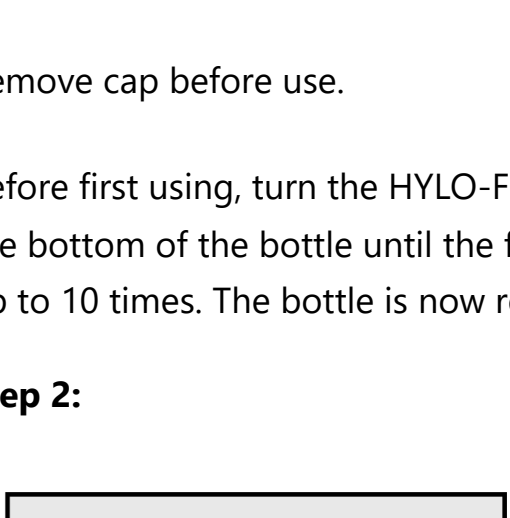
This is particularly important if you wear contact lenses because the contact lenses require sufficient tear fluid in order not to cause discomfort. HYLO-FORTE® may be used while wearing contact lenses. Wearing of both soft and hard contact lenses will be made more comfortable by using HYLO-FORTE® as it does not form crusts or deposits.

As HYLO-FORTE® is preservative-free it is usually well tolerated. HYLO-FORTE® is phosphate-free so that complications such as deposits in the cornea are avoided.

How to use HYLO-FORTE®

Only use HYLO-FORTE® if the sealing of the folding carton was intact before the first use.

Step 1:



Remove cap before use.

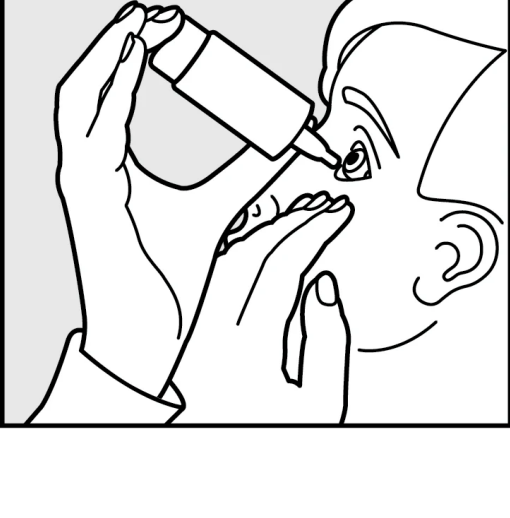
Before first using, turn the HYLO-FORTE® bottle, so that the tip is pointing down and press on the bottom of the bottle until the first drop appears at the nozzle. It may need to be pressed up to 10 times. The bottle is now ready for use.

Step 2:



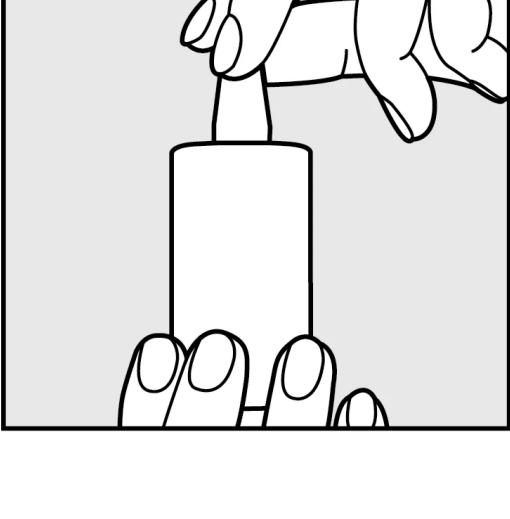
Hold the bottle down with the thumb on the shoulder of the bottle and the other fingers on the bottom of the bottle.

Step 3:



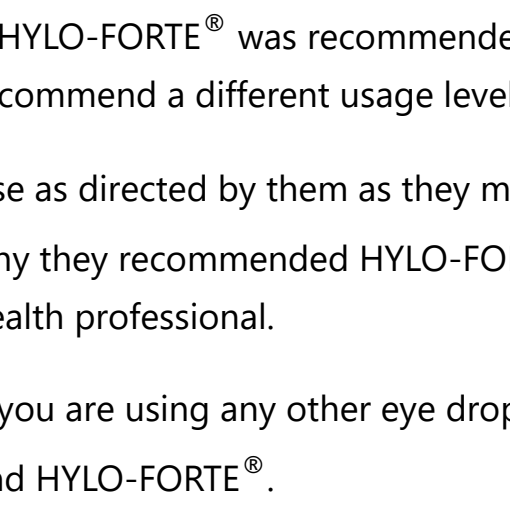
Support the hand holding the HYLO-FORTE® bottle as shown with the other hand.

Step 4:



When applying the eye drops, please avoid any contact between the tip of the bottle and your eye and skin. Lean your head slightly back, gently pull down your lower eyelid and apply a strong, fast pressure onto the bottom of the bottle. This activates the mechanism for the release of one drop. The HYLO-FORTE® valve system ensures that the size and speed of each drop is the same regardless of how much pressure is applied. Slowly close your eyes to allow the fluid to spread evenly on the eye surface.

Step 5:



Replace the cap immediately after use. Take care that the dropper is dry.

A bottle containing 10 mL of HYLO-FORTE® contains approximately 300 drops. After you are unable to obtain any more product from the bottle, you will find that a small amount will be left in the bottle. This is due to technical reasons related to the dropper system.

Typically one drop of HYLO-FORTE®, three times a day is adequate. It may be used more frequently if required. If you need to use HYLO-FORTE® more than 10 times per day or if symptoms persist for longer than one week consult your health professional.

If HYLO-FORTE® was recommended or prescribed by a health professional, they may recommend a different usage level.

Use as directed by them as they may have reasons for this. If you have any questions about why they recommended HYLO-FORTE® to you or the usage level they have advised, ask your health professional.

If you are using any other eye drops, allow at least 30 minutes between using the other drops and HYLO-FORTE® .

HYLO-FORTE® should always be used after any other eye drops.

If using an eye ointment, use HYLO-FORTE® before using the ointment.

To avoid incompatibility reactions that are possible due to interactions between contact lens care products and HYLO-FORTE®, we recommend to wait for about 30 minutes with the application of the eye drops after inserting contact lenses.

According to existing knowledge HYLO-FORTE® can be used in children without limitation of age, pregnant and breast-feeding women.

HYLO-FORTE® can be used long-term and can be used by adults and children. HYLO-FORTE® should be used on the basis of one bottle per person. Bottles should not be shared. For external use only.

Side effects

HYLO-FORTE® is usually well tolerated. In very rare cases adverse reactions like hypersensitivity, burning or excessive watering of the eye, pain, foreign body sensation or other temporary local irritations have been reported. These usually resolve when 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.

Overdose

Because HYLO-FORTE® has a one drop delivery system overdosing should not occur. If you think HYLO-FORTE® has been swallowed, contact your doctor, pharmacist or the Poisons Information Centre (Australia: Telephone 131 126 or New Zealand 0800 POISON or 0800 764 766) or go to the emergency department at your nearest hospital, if you think that you may have used too much or if anyone else has taken HYLO-FORTE® by mistake. Do this even if there are no signs of discomfort or poisoning. Take the pack of HYLO-FORTE® with you if you can.

Storage

Store below 25 °C.

HYLO-FORTE® can be used for up to 6 months after first opening.

Do not use if the product has passed the expiry date printed on the pack.

Keep out of reach of children.

Other ingredients

HYLO-FORTE® also contains a citrate buffer, sorbitol and water.

If you want to know more

If you have any questions regarding this product talk to your doctor, pharmacist, ophthalmologist or other health professionals.

Dispose this product via household waste according to your national legislation. This measure will help to protect the environment.

Distributor

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Date of information: