

Sodium Hyaluronate 2 mg/ml Eye Drops in COMOD system HYLO GEL

Lubricating Eye Drops

HYLO GEL is a preservative free and phosphate free solution.

1. NAME OF THE MEDICINAL PRODUCT.

HYLO GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION.

The bottle contains approximately 300 drops. Each ml of the sterile preservative-free, phosphate free, citrate buffered solution contains 2 mg of sodium hyaluronate.

3. PHARMACEUTICAL FORM.

Eye drops, solution

4. CLINICAL PARTICULARS.

4.1 Therapeutic indications.

HYLO GEL is used for intensive, therapeutic lubrication of the ocular surface in more severe and persisting dry feeling of the eye as well as after surgical interventions on the eye. For symptomatic treatment of corneal and conjunctival dryness (dry eyes syndrome), including severe cases and after surgical interventions.

4.2 Posology and method of administration.

Posology. Normally, three applications of HYLO GEL per day are sufficient but certain patients may require more doses. The patient is asked to consult his eye doctor in case he is using HYLO GEL more frequently (e.g. more than 10 times per day).

Method of administration. For ocular use.

4.3 Contraindications.

Do not use in case of hypersensitivity to any of the ingredients. In the event of persisting eye irritation discontinue use and consult your doctor.

4.4 Special warnings and special precautions for use.

Do not touch the nozzle and do not allow the nozzle tip to touch the eye during use. Do not allow your HYLO GEL to be used by anyone else.

Do not apply HYLO GEL solution at the same time as other eye medications; eye drops can be applied 30 minutes after using HYLO GEL. Ointments should always be applied after using HYLO GEL.

HYLO GEL relieves the symptoms in case of more severe or persistent dry eye sensation. If your eye doctor does not mind if you are wearing contact lenses in spite of this disease, you may use HYLO GEL while you are wearing hard or soft contact lenses. However, in these cases, there may be some smearing on the contact lenses that will disappear after blinking a few times.

4.5 Interaction with other medicinal products and other forms of interaction.

None.

4.6 Fertility, pregnancy and lactation.

No well-controlled studies in pregnant or breast-feeding women exist concerning sodium hyaluronate. Nevertheless, no negative effects on the fetus or the infant are to be expected.

4.7 Effects on ability to drive and use machines.

HYLO GEL eye drops may cause blurred vision for a short time after application even at normal dosages and with proper use. This can subsequently impair reaction time while driving or operating machinery.

4.8 Undesirable effects.

Because it is preservative-free, HYLO GEL is well tolerated even when used over a longer period of time. In very rare cases, hypersensitive reactions like burning or excessive tearing have been reported which stopped immediately after the use of HYLO GEL was discontinued.

4.9 Overdose.

Not applicable.

5. PHARMACOLOGICAL PROPERTIES.

5.1 Pharmacodynamic properties.

Dry eye patients present with instability of the precorneal tear film which breaks up much earlier. Pharmacotherapeutic group: Ophthalmologics/Artificial tears and other preparations, ATC code: S01XA20

For the maintenance of a healthy eye the outer tissue - conjunctiva and cornea - have to be continuously wet. Only then the eye can work properly and complaints are avoided.

In case of dry eye the insufficiency of tears leads to a break up of the tear film on the surface of the eye. Consequently so-called dry spots occur where the epithelial cells come into direct contact with the air and suffer from this.

HYLO GEL contains 0.2 % sodium hyaluronate which is a naturally physiologic substance occurring in the eye but also in other parts of the body.

Sodium hyaluronate is a macromolecular substance with a spiral structure which forms lattice structured polymeric gels already in very low concentrations and has a high hydropexic capacity. It has the specific physico-chemical property to form solutions with non-Newtonian flow characteristics; the solutions are quite viscous, but under the influence of shearing forces the viscosity is reduced (thixotropic properties). In topical use to the eye the applied dose remains for a prolonged period of time in the conjunctival sac but by blinking the viscosity is reduced without impairing vision. The macromolecule sodium hyaluronate has bioadhesive and mucomimetic properties when applied to the eye because



of interactions with the precorneal mucin layer. By this, the solution spreads out very well and forms a stable and long-lasting tear film.

In HYLO GEL, sodium hyaluronate rather acts in a physico-chemical manner by lubricating the ocular surface than having a receptor-related pharmacological effect.

5.2 Pharmacokinetic properties.

Sodium hyaluronate only remains on its target organ, the ocular surface. The substance does not become systemically available and are not metabolised in the human body. It is washed out of the eye after a while.

5.3 Preclinical safety data.

There are no data known about any toxic effect of sodium hyaluronate.

Because sodium hyaluronate is a naturally physiologic substance occurring in the eye but also in other parts of the body, the substance is very well tolerated in general.

6. PHARMACEUTICAL PARTICULARS.

6.1 List of excipients.

Citric acid, anhydrous IP, Sodium citrate IP, Sorbitol IP, Water for injections IP

6.2 Incompatibilities.

None known

6.3 Shelf life.

Refer to pack. Refer to the outer carton for the date of expiry. The date of expiry is the last day of the month. Use the solution within 6 months of opening the container.

6.4 Special precautions for storage.

Do not store above 25°C.

Store this drug out of reach from children.

6.5 Nature and contents of container.

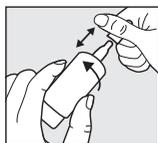
Multidose plastic container with airless pump and dropping applicator. One bottle contains 10 ml of solution.

6.6 Instructions for use and handling.

WARNING: (i) If irritation persists or increases, discontinue the use and consult the physician. (ii) Do not touch the dropper tip or dispensing tip to any surface since this may contaminate solutions.

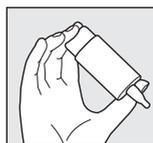
How should HYLO GEL be applied?

Use HYLO GEL only if the sealing of the folding carton is intact before the first use.

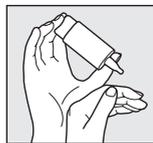


Remove cap before use.

For this purpose, hold the cap just over 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 GEL bottle with its tip down and press onto the bottom of the bottle until the first drop appears at the nozzle. Now the bottle is ready for further use.



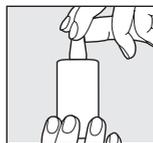
Hold the bottle upside down with the thumb on the shoulder of the bottle and the other fingers on the bottom of the bottle.



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



Lean your head back slightly, gently pull down your lower eyelid and apply a strong and quick pressure on the middle of bottom of the bottle. This activates the mechanism for the release of one drop. Due to the special COMOD valve system, size and speed of each drop are the same no matter how much pressure is applied. Slowly close your eyes to allow the fluid to spread evenly on the eye surface.



Replace cap immediately after use. Take care that the dropper tip is dry. When applying the fluid please avoid any contact between the tip of the bottle and your eye or your skin.

The COMOD-bottle releases 10 ml of solution which is the equivalent of approximately 300 drops.

For technical reasons a small amount remains in the bottle at the end of exhaustion.

HYLO GEL is suitable for long term treatment.

One bottle HYLO GEL should be used only by the same person.

Manufactured by:

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Imported and marketed in India by:

URSAPHARM India Pvt. Ltd.

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