SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

HYLO-COMOD®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of eye drop solution contains:
Sodium hyaluronate …… 1.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution

pH: 6.8-7.6
Osmolality: 240-290 mOsm/kg

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

HYLO-COMOD® is used to lubricate and rewet the surface of the eye. HYLO-COMOD® is thus indicated as an ocular lubricant for dry, burning, or irritated eyes due to reduced lacrimal secretion which can be caused by topical disease, by mechanical failure of eye closure or due to ophtalmoglogical interventions.

4.2 Posology and method of administration

Posology

Normally, three applications of HYLO-COMOD® per day are sufficient but certain patients may require more doses. If any doubt, consult your doctor or pharmacist.

Method of administration

For ocular use.

4.3 Contraindications

HYLO-COMOD® should not be used in case of a hypersensivity or allergy to one of the ingredients.

In the event of persisting eye irritation discontinue use and consult your doctor.

4.4 Special warnings and precautions for use

As general rule, contact of the bottle tip with eye or skin surface should be avoided when applying eye drops.
Only one person should be treated with one particular bottle of HYLO-COMOD® in order to reduce the risk of cross-infections.

4.5 Interaction with other medicinal products and other forms of interaction

HYLO-COMOD® is not known to be affected by other medicines.
If you use any other eye drops there should be at least 30 minutes between the applications and HYLO-COMOD® should always be used last. Eye ointments should, however, always be administered after using HYLO-COMOD®.

4.6 Fertility, pregnancy and lactation

According to existing knowledge HYLO-COMOD® can be used in children, pregnant and breast-feeding women.

4.7 Effects on ability to drive and use machines

Temporary blurred vision is possible after application of HYLO-COMOD® due to the viscosity of the eye drops solution. This can subsequently impair reaction time while driving or operating machinery.

4.8 Undesirable effects

The assessment of undesirable effects is based on the following frequencies:
Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1.000 to <1/100)
Rare (≥ 1/10.000 to < 1/1.000)
Very rare (<1/10.000)
Unknown (Incidence cannot be estimated from the available data.)

Very rare:
Adverse reactions like hypersensitivity, burning or excessive tearing, pain, foreign body sensation or other temporary local irritations have been reported which stopped when the use of HYLO-COMOD® was discontinued.

Please note that temporary blurred vision is possible after application of HYLO-COMOD® due to the viscosity of the eye drops solution. In very rare cases this may cause temporary headache in sensitive patients.

Additionally, HYLO-COMOD® is free of phosphates so that complications like deposits in the cornea are avoided.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS)
https://pv.pharmacyboardkenya.org

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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-COMOD® contains 0.1 % 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-COMOD®, 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, sodium citrate, sorbitol and water for injections.

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years

HYLO-COMOD® eye drops can be used up to 12 weeks after the bottle has been opened.

The drug should not be used beyond the expiry date (imprinted on the packaging carton).

6.4 Special precautions for storage

Do not store above 25°C.

Store this drug out of reach and sight of children.

6.5 Nature and contents of container

Multi-dose container with airless dropping pump and cap containing 10 ml of solution.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORIZATION NUMBER

16485

9. DATE OF FIRST AUTHORIZATION

Date of first authorisation: 30 November 2005

10. DATE OF REVISION OF THE TEXT

01/2026, 12th August 2026