

Hyacarenol

(Sodium hyaluronate / Dexpanthenol) eye drops

1. NAME OF THE MEDICINAL PRODUCT

Hyacarenol eye drops

2. Generic name:

Sodium hyaluronate / Dexpanthenol

3. Pharmaceutical form:

Eye drops.

4. Composition:

Each 1 ml of solution contains

Active ingredient:

Sodium hyaluronate 1 mg

Dexpanthenol 20 mg

Inactive ingredients:

Sodium chlorite, Hydrogen peroxide, Propylene glycol, Calcium chloride dehydrate, Potassium chloride, Sodium chloride, Magnesium chloride hexahydrate, Sodium borate decahydrate, Boric acid, Sodium hydroxide/HCL PH Adjusting, Water for injection

5. Indications and usage:

Hyacarenol is indicated for Symptomatic dry eye syndrome as it contains sodium hyaluronate. & because of dexpanthenol Hyacarenol used For symptomatic treatment of dehydration of the cornea and conjunctiva due to tear secretion disorders due to local or systemic underlying diseases as well as lack of eyelids. For hard contact lenses for rewetting during the wearing. Hyacarenol is used in adults.

6. Dosage and administration:

Dosage

Unless otherwise prescribed, drip 1 drop into the conjunctival sac 4 times a day.

Maximum dosage up to 8 times 1 drop per day.

Various studies showed, however, that more than 4 times a day applications will not lead to any further improvement.

Hyacarenol is suitable for long-term therapy.

Hyacarenol should not be at increased risk of infection of the inner and outer eye (e.g., after eye surgery or infection-prone patients) become.

Hyacarenol is not recommended for use in children under 18 years due the lack of experience.

Eye drops should always be applied so that contact of the dropper with the eye or facial skin is avoided.

In general, tear substitutes must be dripped for life. Exceptions are temporary secondary symptoms that are provoked by medication or primary disease.

Method of administration :

For use on the eye.

In the case of an additional other drug treatment on the eye should be an application interval of at least 5 minutes must be observed. Hyacarenol always administer last.

There is only experience with patients over 18 years old.

7. Contraindications

Hypersensitivity to the active substance or to any of the excipients.

8. Warning and Precautions:

Studies on the influence of Hyacarenol on the intraocular pressure or on influencing the measurement results are not available.

Hyacarenol may be given while wearing contact lenses, as long as the ophthalmologist advocates the use of contact lenses for the underlying disease.

Contact of the dropper with the eye or facial skin is to be avoided.

9. Adverse reaction:

The evaluation of side effects is based on the following frequencies:

Very often, more than 1 in 10 people may be affected

Common may affect up to 1 in 10 people

Occasionally, up to 1 in 100 people may be affected

Rarely can affect up to 1 in 1000 people

Very rarely can affect up to 1 in 10,000 people

Not known Frequency can not be estimated from the available data

Occasionally there may be a temporary burn immediately after use.

When used as intended, in rare individual cases

Hypersensitivity reactions that manifest themselves in mild burning or increased tear fluid occur.

Report of suspected adverse reactions

Reporting suspected adverse reactions after approval is of great importance. It allows continuous monitoring of the benefit-risk balance of the drug. Healthcare professionals are required to report any suspected adverse reactions to Egyptian Pharmacovigilance center at Ministry of Health.

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

No interaction studies have been performed.

If other eye drops or eye ointments are used in addition, a time interval of 15 minutes between the applications of the individual preparations should be observed. Eye ointments should always be used last.

11. Fertility, pregnancy and lactation

- Sodium hyaluronate reproduction studies have shown no risks, but there are no controlled studies in pregnant women.
- Dexpanthenol has no clinical data on exposed pregnancies.

Animal studies do not indicate any direct or indirect harmful effects on pregnancy, embryonal / fetal development, parturition or postnatal development.

If used during pregnancy, caution is recommended.

At the moment, there are no clinical data on lactation or fertility.

12. Effects on ability to drive and use machines

It may appear blurred vision for a short time after application until evenly distributed eye drops. This must be taken into account when operating machines and on the road

13. Overdosage

No cases of overdoses were reported.

14. PHARMACOLOGICAL PROPERTIES

14.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other ophthalmic, artificial tears and other preparations

ATC code: S01XA20

Hyaluronic acid is a naturally occurring mucopolysaccharide. In humans, they are found mainly in skin, connective tissue, bone and in the vitreous body of the eye.

Hyacarenol contains hyaluronate in the form of its sodium salt. mechanism of action

It is produced biotechnologically, using a natural strain of *Streptococcus*. Sodium hyaluronate rheologically exhibits non-Newtonian behavior with relatively high quiescent viscosity which reduces drainage through the lacrimal duct and prolongs Sodium hyaluronate retention time in the eye. This rheological property is supported by the carbomer. In contrast, the shearing forces of blinking movements reduce the viscosity of Hyacarenol and allow the eyelids to glide well on the cornea.

Dexpanthenol (= panthenol) is a precursor of pantothenic acid (vitamin B5) and is metabolized in the organism to this. Pantothenic acid is part of coenzyme A, which is essential as acetyl coenzyme A for the degradation of fats, carbohydrates and various amino acids. Coenzyme A is present in higher concentrations in all organs in which a high metabolism takes place; the highest content is found in the skin. Since there is a local deficiency of coenzyme A in injuries of the epithelium and the deeper layers, the topical application proves to be particularly effective, not least because of the good penetration capacity of the dexpanthenol, as particularly effective.

Dexpanthenol leads by its granulation-promoting, anti-inflammatory, re-epithelializing and antipruritic effect to a rapid healing of bacterial inflammation of the eye.

14.2 Pharmacokinetic properties

Hyacarenol has a purely physical effect on the eye and is not absorbed.

With the application of the drop the destination of the efficacy is reached.

15. Storage

Store at temperature not exceeding 30 °C, in a dry place.

And after opening store at temperature not exaceeding 30 °C for 28 days .

Keep out of reach of children.

Shelf life : 2 years

16. Package:

Carton box contains sterile opaque white LDPE plastic bottle containing 10 ml eye drops solution with a white HDPE Nozzle and opaque white PP screw cap + insert leaflet.

Manufactured by
Rameda For Sanocare Scientific