

Hydratears

(Sodium hyaluronate) Eye drops

1. NAME OF THE MEDICINAL PRODUCT

Hydratears eye drops

2. Generic name:

Sodium hyaluronate

3. Pharmaceutical form:

Eye drops.

4. Composition:

Each 1 ml of solution contains

Active ingredient:

Sodium hyaluronate 1.5 mg

Inactive ingredients:

Sodium chlorite, Hydrogen peroxide, glycerin, Calcium chloride dihydrate, Potassium chloride
Sodium chloride, Magnesium chloride hexahydrate, Sodium borate decahydrate, Boric acid
Sodium Hydroxide/HCl, Water for injection

5. Indications and usage:

Hydratears is indicated for Symptomatic dry eye syndrome.

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.

Hydratears is suitable for long-term therapy.

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

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

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. Hydratears 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 Hydratears on the intraocular pressure or on influencing the measurement results are not available.

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

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

- So far none known

11. Fertility, pregnancy and lactation

- Reproduction studies have shown no risks, but there are no controlled studies in pregnant women.

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

An overdose has not been observed so far

14. PHARMACOLOGICAL PROPERTIES

14.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other ophthalmic, artificial tears and other preparations

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.

Hydratears 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.

Glycerin is hygroscopic and supports the retention of water on the cornea and conjunctiva.

14.2 Pharmacokinetic properties

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

15. Storage

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

And after opening store at temperature not exceeding 30 °C for 4 weeks .

Keep out of reach of children.

Shelf life : 2 years

16. Package:

Carton box contains sterile opaque white LDPE plastic bottle has a capacity of 15 ml containing 10 ml transparent colorless solution, free of visible particulate matters with a white HDPE Nozzle and opaque white PP screw cap + inner leaflet.

Manufactured by
Rameda For Sanocare Scientific