HealTears® Eye Drops PINK

1. **Generic Name**
   Sodium Hyaluronate and Trehalose Eye drops.

2. **Qualitative and Quantitative Composition**
   Sodium Hyaluronate BP…….0.18% w/v
   Trehalose USP……3.0% w/v
   Aqueous buffered vehicle ……. q.s.

3. **Dosage form and strength**
   Topical ophthalmic solution containing Sodium Hyaluronate 0.18% w/v and Trehalose 3.0% w/v

4. Clinical particulars

4.1 Therapeutic indication

HealTears Pink ophthalmic solution is indicated for the treatment of ocular dryness, and other minor complaints of no pathological significance like burning and ocular fatigue induced for example by dust, smoke, dry atmosphere, air conditioning, extended computer screen use or contact lens wear.

4.2 Posology and method of administration

One drop thrice daily in the interval of 8 hours or as directed by physician.

4.3 Contraindication

HealTears Pink is contraindicated in patients with a history of hypersensitivity to Sodium Hyaluronate or Trehalose or any of the ingredients in the formulation.

4.4 Special warnings and precautions for use

- For ocular use only.
- If solution changes colour or becomes cloudy, do not use.
- To avoid contamination, never touch the solution tip of the container to any surface.
- Contact lenses should be removed before each application and may be inserted after 15 minutes of application.
- Replace cap after using.

- Stop using and consult eye care professional if you experience:
  - Persistent eye discomfort
  - Vision changes
  - Excessive tearing
  - Redness of the eye

4.5 Drug interactions

None reported.

4.6 Use in special population

- Paediatric: Consult ophthalmologist before use
- Geriatric: Consult ophthalmologist before use
- Liver impairment: Consult ophthalmologist before use
- Renal failure: Consult ophthalmologist before use
- Pregnancy and lactation: Use with caution.

4.7 Effects on ability to drive and use machine

HealTears Pink may temporarily cause blurred vision right after being placed in the eye(s). Do not drive, use machinery, or do any activity that requires clear vision until you are sure you can perform such activities safely.

4.8 Undesirable effects

Temporary side effects like blurred vision, minor burning, stinging, irritation may occur.

4.9 Overdose

There is limited experience of overdose with HealTears Pink. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

The effect of Hyaluronate in the treatment of Dry Eye Syndrome (DES) is likely the result of various mechanisms of action. Firstly, *in-vitro* studies have demonstrated that Hyaluronate inactivates the CD44 adhesion molecule, a receptor of Hyaluronate found to be over expressed in cornea and conjunctiva cells of subjects with DES. This Hyaluronate-CD44 interaction has been shown to stabilise the ocular surface barrier and tear film, creating a favourable ocular surface microenvironment which increases cell adhesion and motility and promotes cellular migration.

Second, Hyaluronate has been postulated to have localised anti-inflammatory effects – particularly in patients with at least moderate dry eyes and superficial keratitis. Third, the high viscosity of Hyaluronate reduces friction between the cornea and eyelids during extraocular movements and blinking, therefore reducing mechanical damage of the cornea. At last,

Hyaluronate has significant water-retentive properties – with an affinity of 1000-fold its own weight. This increases ocular surface wettability and reduces tear evaporation.

Sodium Hyaluronate (SH) can improve the stability of the tear film, facilitate the healing of corneal epithelial injury, improve the integrity of corneal epithelial cells, and thus optimize the clinical treatment of dry eye.

Trehalose has been found to have several potential benefits for the management of DED. Firstly, trehalose can stabilize the lipid layer of the tear film, which is essential for maintaining tear-film stability and preventing evaporation. Secondly, trehalose can reduce tear-film osmolarity, which is often elevated in DED and contributes to ocular surface damage. Thirdly, trehalose has been shown to enhance the survival of corneal epithelial cells, which are essential for maintaining the integrity and function of the ocular surface. Lastly, trehalose has anti-inflammatory properties and can modulate the expression of genes involved in the regulation of tear secretion and ocular surface homeostasis.

5.2 Pharmacodynamic Properties

Hyaluronate increases the stability of the pre-corneal tear film, which protects the ocular surface from environmental agents, and it has water retentive properties, which improve ocular surface wettability. It may also contribute to a favourable microenvironment during ocular repairing processes. It also has visco-elastic properties that can lubricate the ocular surface reducing friction during blinking and ocular movements.

Trehalose, a natural disaccharide consisting of two glucose molecules, has been shown to have protective properties against various stressors and is known to stabilize proteins and membranes, prevent denaturation and inhibit oxidative damage.

5.3 Pharmacokinetic properties

Sodium Hyaluronate eye drops reach their target directly by topical application and have primarily a physical effect (wetting of the surface). The substance does not become systemically available and is not metabolised in the human body. It is washed out of the eye after a while.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

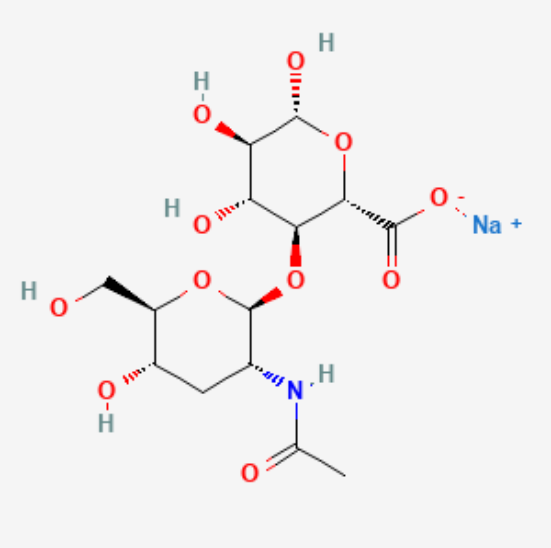
Three New Zealand white rabbits each received 0.1 mL of a 0.2% NaHA solution, placed into the lower everted lid of one eye of each animal. The eyes were examined after 1 hour and 1,2, 3, 4 and 7 days after instillation of the test material. In this study, effects on the eye were tested at more dilute concentrations of NaHA, because the viscous nature of 1 % NaHA precludes its use in this kind of experiment. The sample did not elicit a positive response in any of the three treated animals according to OECD test criteria.

Trehalose was instilled at a volume of 0.1 ml of a 10% solution into the right eye of each of six New Zealand white rabbits. The left eye of each animal was used as a control, and each eye was scored for irritation 1, 24, 48, and 72 h after application. The study was terminated at day 4. There

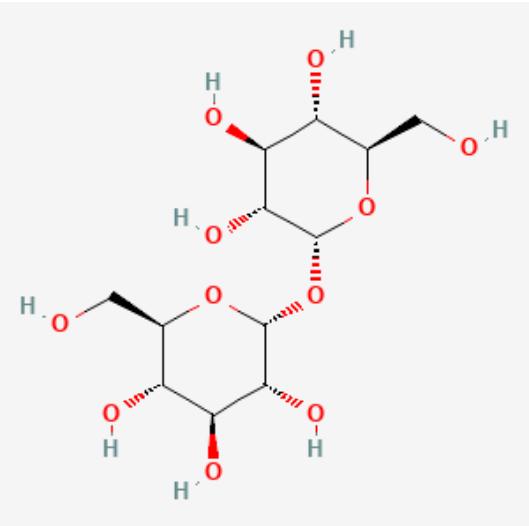
were no deaths or signs of systemic toxicity and no evidence of irritation to the cornea, iris, or conjunctivae. Under the conditions of this assay, trehalose was not an eye irritant.

7. Description

Sodium hyaluronate is sodium (2*S*,3*S*,4*R*,5*R*,6*R*)-3-[(2*S*,3*R*,5*S*,6*R*)-3-acetamido-5-hydroxy-6-(hydroxymethyl) oxan-2-yl]oxy-4,5,6-trihydroxyoxane-2-carboxylate, with the empirical formula $C_{14}H_{22}NNaO_{11}$, a molecular weight of 403.31 g/mol, and the following structural formula:



Alpha, alpha-trehalose is a trehalose in which both glucose residues have alpha-configuration at the anomeric carbon. Trehalose has shown protective properties against various stressors and is known to stabilize proteins and membranes, prevent denaturation and inhibit oxidative damage. Trehalose is alpha-D-gluco-hexopyranosyl alpha-D-gluco-hexopyranoside with the empirical formula $C_{12}H_{22}O_{11}$, a molecular weight of 342.30 g/mol, and the following structural formula:



8. Pharmaceutical particulars

8.1 Incompatibilities
There are no known incompatibilities.

8.2 Shelf-life
24 months

8.3 Packaging Information
10ml sales: 5ml PS

8.4 Storage and handling instructions
Store in a cool & dry place at a temperature not exceeding 30°C. Protect from light. Do not allow to freeze. Keep the medicine out of reach of children

9. Patient Counselling Information

9.1 Adverse Reactions
Refer part 4.8

9.2 Drug Interactions
Refer part 4.5

9.3 Dosage
Refer part 4.2

9.4 Storage
Refer part 8.4

9.5 Risk Factors
Refer part 4.4

9.6 Self-monitoring information
NA

9.7 Information on when to contact a health care provider or seek emergency help
Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8. Contraindications
Refer part 4.3

10. Manufactured in India by:

Centaur
We Impart Health to Life

ABLE PHARMA
Village Gullarwala, Sai Road, Baddi,
Distt.- Solan - 173 205 (H.P.), India.
(WHO-GMP Certified Unit)

11. Manufacturer license number: MB/06/490 & MNB 06/489
Dated: 27/03/2025

12. Date of revision: October 2026