HealTears® Xtra

1. Generic Name

Sodium Hyaluronate Ophthalmic Solution 0.18%w/v.

2. **Qualitative and Quantitative Composition**

Sodium Hyaluronate BP ……... 0.18%w/v
Stabilized Oxychloro complex …….. 0.005%w/v
(As preservative)
Sterile Aqueous Buffered vehicle ……. q.s

3. Dosage form and strength

Topical ophthalmic solution containing Sodium Hyaluronate 0.18% w/v.

4. Clinical particulars

4.1 Therapeutic indication

HealTears Xtra ophthalmic solution is indicated to provide temporary relief from burning and irritation due to dryness of the eye.

4.2 Posology and method of administration

Apply half an inch ribbon into the affected eye(s) as needed or as directed by the physician.

4.3 Contraindication

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

4.4 Special warnings and precautions for use

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

Not known.

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 Xtra 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 Xtra. 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.

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.

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.

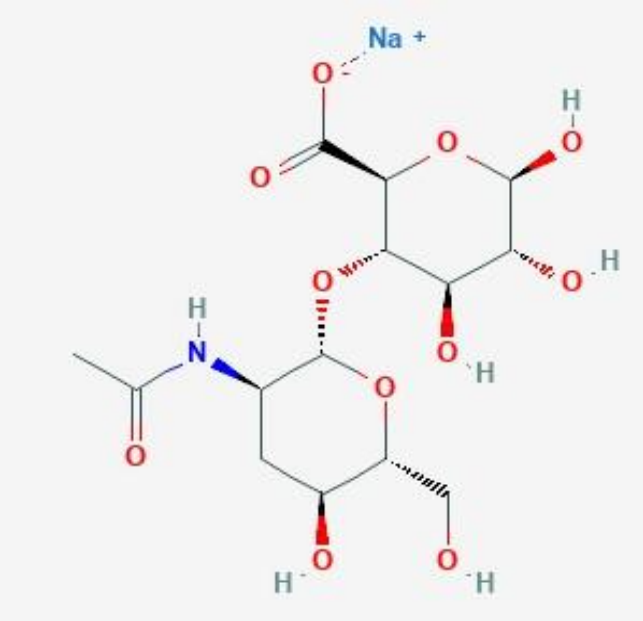
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Not required.

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:



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months.

8.3 Packaging Information

HealTears Xtra is available in a pack of 10 gm and 5gm.

8.4 Storage and handling instructions

Store in a dry, well-ventilated place at a temperature not exceeding 25^0C.
Protect from light. Do not freeze. Sterile until opened.

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
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