1. Generic Names

Sodium Hyaluronate BP

2. Qualitative and Quantitative Composition

Sodium Hyaluronate BP	……	0.1% w/v
Stabilised Oxychloro Complex(As preservative)	……	0.01% w/v
Sterile aqueous vehicle	……	q.s.

Other ingredients- D-Panthenol IP, Sodium Carboxymethylcellulose IP, Erythriol BP, Levocarnithine BP, Glycerine IP, Potassium Chloride IP, Calcium Chloride IP, Magnesium Chloride IP, Sodium Chloride IP, Boric Acid IP, Borax IP, Sodium Citrate IP.

3. Dosage form and strength

Topical ophthalmic solution containing Sodium Hyaluronate BP 0.1%(0.1mg/100ml).

4. Clinical particulars

4.1 Therapeutic indication

HealTears ophthalmic solution is indicated for:

- Mild to severe dry eyes
- Post operated dry eyes
- Corneal burns

4.2 Posology and method of administration

Instill HealTears into affected eye(s) as directed by the ophthalmologist.

4.3 Contraindication

HealTears 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

- Contamination of Tip and Solution

If irritation persists or increases, discontinue the use and consult physician.

Do not touch the dropper tip or other dispensing tip to any of surface since this may contaminate the solution.

Care should be taken to avoid contamination of solution during use

Use the solution within one month after opening the container.

- Contact lens use

Avoid using HealTears while wearing contact lens

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: Consult ophthalmologist before use.

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to HealTears is known.

4.8 Undesirable effects

Most common reported adverse reactions are:

- Blurred vision
- Eye redness or discomfort or other irritation not present before use of this medicine
- Increased sensitivity of eyes to light
- Matting or stickiness of eyelashes
- Swelling of eyelids
- Watering of eye

4.9 Overdose

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

5. Pharmacological properties

5.1 Mechanism of action

Sodium hyaluronate is a thick elastic polymer that is found naturally throughout the body, particularly in areas of the body that need lubrication, such as the joints and the structures of the eye. Sodium hyaluronate film is able to 'hold on' to water molecules in the tears, which helps keep the eyeball moist, and remains stable while blinking, thus providing lasting lubrication for the eyes. It also promotes corneal epithelial wound healing by rapid migration of cells leading to rapid wound closure. This may be facilitated by the adhesion between CD44 on the cells and hyaluronic acid, which coats the surface of the denuded cornea.

CMC is beneficial in increasing tear retention time and lubricating ocular surface.

Erythriol and Glycerine acts as osmoprotectant and counteract the effects of hyperosmolarity.

Levocarnithine BP protects retinal pigment epithelial cells from oxidative damage and hyperosmotic stress.

D-Panthenol is necessary in the processes of reconstruction of epithelium, has regenerative and anti- inflammatory properties.

5.2 Pharmacodynamics properties

Hyaluronic acid is similar to a substance that occurs naturally in the joints. It may work by acting as a lubricant and shock absorber in the joint, helping the knee to move smoothly, there by lessening pain**.**

5.3 Pharmacokinetic properties

Sodium Hyaluronate 0.1% 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

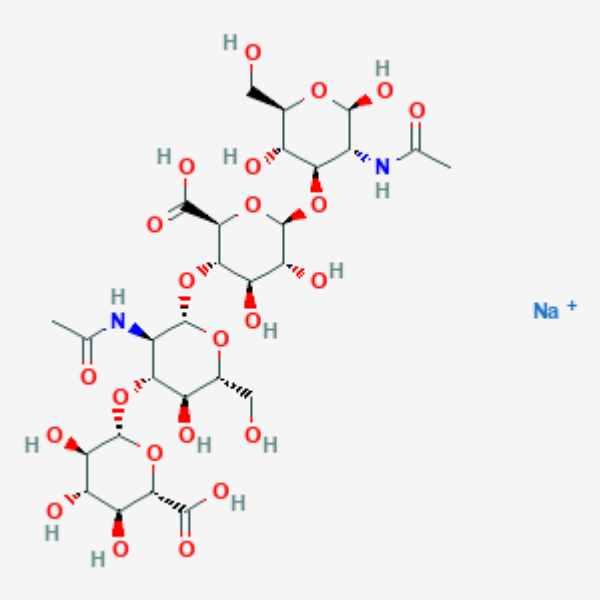
6.1 Animal Toxicology or Pharmacology

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.

7. Description

A natural high-viscosity mucopolysaccharide with alternating beta (1-3) glucuronide and beta (1-4) glucosaminidic bonds. The chemical name is sodium;(2*S*,3*S*,4*S*,5*R*,6*R*)-6-

[(2*S*,3*R*,4*R*,5*S*,6*R*)-3-acetamido-2-[(2*S*,3*S*,4*R*,5*R*,6*R*)-6-[(2*R*,3*R*,4*R*,5*S*,6*R*)-3-acetamido-2,5-dihydroxy-6-(hydroxymethyl)oxan-4-yl]oxy-2-carboxy-4,5-dihydroxyoxan-3-yl]oxy-5hydroxy-6-(hydroxymethyl)oxan-4-yl]oxy-3,4,5-trihydroxyoxane-2-carboxylic acid Its empirical formula and molecular weight is $C_{28}H_{44}N_2NaO_{23}^+$ and 799.6 g/mol.



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

18 months.

8.3 Packaging Information

HealTears is available in a pack of 10ml

8.4 Storage and handling instructions

Store below 25°C.

Protect from light.

Do not freeze.

Keep out of the reach 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 by CENTAUR PHARMACEUTICALS PVT. LTD.

11. Details of permission or license number with date

158(458)/MFG/DFDA/2018/3179 dated. 28.11.2018 for domestic.

12. Date of revision: January 2021