

HEALTEARS PLUS

Prescribing Information:

1. Polyethylene glycol + Propylene glycol 2. Qualitative and Quantitative composition

Polyethylene glycol.....	0.4% w/v
Propylene glycol.....	0.3% w/v
Stabilized Oxychlorocomplex (As preservative).....	0.0075%
Sterile Buffered Isotonic Aqueous vehicle.....	qs

3. Dosage form and strength

Topical ophthalmic solution containing Polyethylene glycol 0.4% and Propylene glycol 0.3%.

4. Clinical particulars

4.1 Therapeutic indication

HealTears Plus ophthalmic solution is indicated for temporary relief of burning and irritation due to dryness of the eye.

4.2 Posology and method of administration

Instill one or two drops in the eye(s) as needed or as directed by the physician.

4.3 Contraindication

HealTears Plus is contraindicated in patients with a history of hypersensitivity to Polyethylene glycol or Propylene glycol 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.
- To avoid contamination, never touch the dropper tip of the container to any surface.
- Contact lenses should be removed before each application and may be inserted after 15 minutes of eye drop instillation.
- 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

- Pediatric: 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 Plus 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 Plus. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

Eye Drops contains polyethylene glycol and propylene glycol which forms stabilized crosslinked muco-mimetic layer thus, it prolongs the Tear break-up time (TFBUT) and provides the better lubrication & visual acuity. It also supports effective protection to the corneal epithelium. **5.2 Pharmacodynamic properties**

Polyethylene glycol (PEG) is a demulcent that forms a protective layer over a mucous membrane to relieve inflammation or irritation and to preserve the ocular surface microenvironment.

Propylene glycol forms a protective layer over mucous membranes to relieve inflammation and/or irritation. It also increases the viscosity of the eye drop. In addition to its demulcent properties, propylene glycol is a humectant because it holds up to three times its own weight in water.

5.3 Pharmacokinetic properties

No data available.

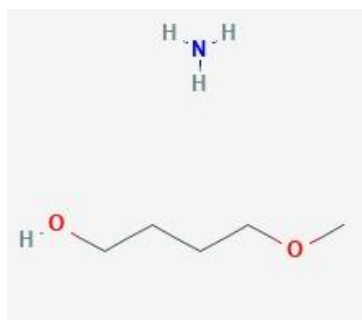
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

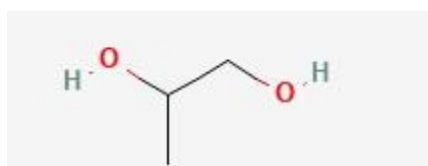
Not required.

7. Description

Polyethylene glycol is azane;4-methoxybutan-1-ol, with the empirical formula $C_5H_{15}NO_2$, a molecular weight of 121.18, and the following structural formula:



Propylene glycol is propane-1,2-diol, with the empirical formula $C_3H_8O_2$, a molecular weight of 76.09, 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 Plus is available in a pack of 10ml

8.4 Storage and handling instructions

Store in a cool and dry place away from sunlight

9. Patient Counselling Information

9.1 Adverse reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.8

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. Manufacturer lic no. 599 B(H)

12. Date of revision: Feb 2023