RELUB® DS Gel

1. Generic Names

Carboxymethylcellulose IP

2. Composition

Carboxymethylcellulose IP 1% w/v

3. Dosage form and strength

Topical ophthalmic solution containing Carboxymethylcellulose IP 1% (1mg/100ml)

4. Clinical particulars

4.1 Therapeutic indication

To preserve the benefits of cataract and refractive surgery since post-surgery dry eye syndrome shows up.

4.2 Posology and method of administration

As directed by physician.

4.3 Contraindication

Hypersensitivity to any components of Relub DS.

4.4 Special warnings and precautions for use

- Remove contact lenses before using this eye drop.
- To avoid contamination do not touch tip of container to any surface. Replace cap after using.
- Do not use if solution changes colour or becomes cloudy.
- Keep out of reach of children.

- This product 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.
- If you experience eye pain, changes in vision, continued redness or irritation of the eye and if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.

4.5 Drug interactions

No drug interactions for Relub DS are reported.

4.6 Use in special population

- Pediatric: Safety in children has not been established.
- Geriatric: Safety in elderly patient has not been established.
- Liver impairment: No data available.
- Renal failure: No data available.
- Pregnancy and lactation: Safety during pregnancy and breast feeding has not been established.

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 Relub DS is known.

4.8 Undesirable effects

Relub DS Eye Drops rarely causes serious side effects or an allergic reaction. Vision may be temporarily blurred when this product is first used. Minor burning, stinging or irritation may temporarily occur.

4.9 Overdose

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

5. Pharmacological properties

5.1 Mechanism of action

Carboxymethylcellulose binds to the surface of corneal epithelial cells via its glucopyranose subunits binding to glucose receptors GLUT-1. The residence time of Carboxymethylcellulose bound to corneal cells is approximately 2 hours as indicated by a short-term binding assay. Binding of Carboxymethylcellulose to the matrix proteins stimulated corneal epithelial cell attachment, migration, and re-epithelialization of corneal wounds

5.2 Pharmacodynamics properties

In a randomized clinical study of patients with mild or moderate forms of eye dryness, ophthalmic treatment with sodium Carboxymethylcellulose resulted in a diminished frequency of symptoms compared to the placebo group. Carboxymethylcellulose interacts with human corneal epithelial cells to facilitate corneal epithelial wound healing and attenuate eye irritation in a dose-dependent manner. It exhibits protective actions on the ocular surface in various applications; it mediates cytoprotective effects on the ocular surface when applied prior to contact lenses and reduces the incidence of epithelial defects during LASIK

5.3 Pharmacokinetic properties

Not available.

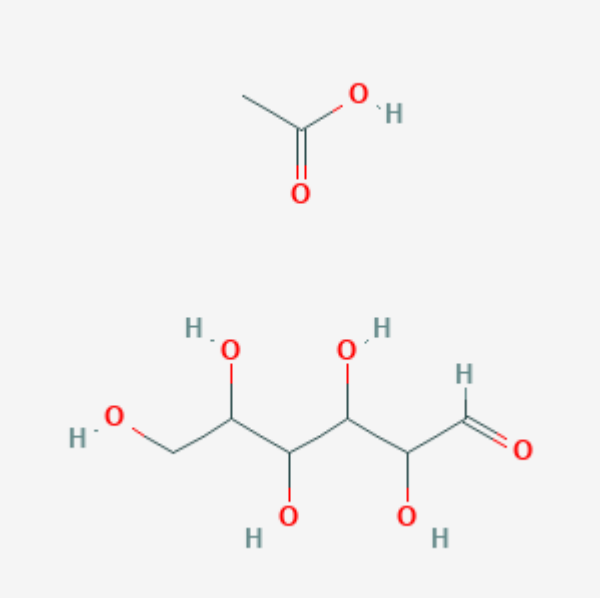
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

A cellulose derivative which is a beta-(1,4)-D-glucopyranose polymer. The chemical name is acetic acid;2,3,4,5,6-pentahydroxyhexanal It is used as a bulk laxative and as an emulsifier and thickener in cosmetics and pharmaceuticals and as a stabilizer for reagents. Its empirical formula and molecular weight is $C_8H_{16}O_8$ and 240.21 g/mol.



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months.

8.3 Packaging Information

Relub DS Eye drops is available as a sterile plastic vial of 10 ml.

8.4 Storage and handling instructions

Store below 25° C in a dry place. Protect from light.

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

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