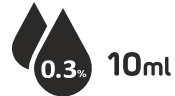


AacuLose

Hypromellose 0.3% w/v Eye Drops



Instructions for Use

It is important to read this leaflet carefully before using AacuLose eye drops. The information provided summarises the important points about the product but if you have any further questions then please ask your doctor, pharmacist or optician.

1. Dosage form:

Ophthalmic Solution.

2. Composition:

Hydroxy Propyl Methyl Cellulose Sodium BP0.3%w/v
Benzalkonium Chloride BP0.01%w/v
Water for Injections BP q.s.

3. Intended Use:

Temporary dry eye relief, burning and ocular fatigue and other minor complaints of no pathological significance induced, for example, by dust, smoke, dry heat, air conditioning, wind, cold, extended computer screen use or contact lens wear (rigid or soft).

4. Mode of Action:

Sterile Hydroxy Propyl Methyl Cellulose (HPMC) Eye Drops is considered an inert substance as it has no direct pharmacological activity. The viscosity promoting properties of HPMC eye drops prolong the retention time and improve adhesion of synthetic tears to the cornea and conjunctiva. As a result, the tear film breakdown time is prolonged and/or the tear film stability is enhanced. A stable tear film protects the cornea from dryness and epithelial cells.

5. Instructions for Use:

Before opening a new bottle of AacuLose Eye Drops, please check that the safety ring on the cap of the bottle is unbroken.

1. Wash and dry your hands well before use.
2. Rotate the cap anti clockwise to break the seal.
3. Remove the cap.
4. Tilt your head back and look up.
5. Gently pull down the lower lid of the eye to form a small pocket between your eyelid and your eye.
6. Hold the bottle between your thumb and middle finger of your other hand and with your index finger apply moderate pressure to base of the eye drop bottle to release one drop of AacuLose into the pocket.
7. Blink your eye a few times.
8. If you think that you have missed the eye, then insert another drop.
9. Carefully wipe away any excess AacuLose eye drops around the eyelid with a lint free tissue.
10. Repeat the process for the other eye, if required.
11. Replace the cap on the container, trying not to touch the applicator tip with anything, including the eye or your fingers.

6. Dosage & Administration:

Instill 1 to 2 drops in the affected eye(s) as directed.

7. Contraindications:

- Do not use if corneal abrasion, ocular infection, foreign body trapping or ocular trauma is suspected.
- Do not use if user is hypersensitive/allergic to the Hydroxy Propyl Methyl Cellulose or any other content of device.

8. Warning & Precautions:

- Do not use if the safety ring on the cap of the vial is broken.
- Do not use if you are allergic to any of the ingredients.
- Do not touch the tip of the vial with your eye or any surface.

- Do not share AacuLose 0.3% Eye Drops with any other person.
- AacuLose 0.3% Eye Drops can cause eye irritation, or transient mild burning sensation and blurring of vision after application. Wait until your vision is clear before driving or using machinery.
- Do not use after the expiry date shown on the carton or printed on the vial.
- Leave at least 30 minutes between administrations of any other ophthalmic drugs.
- Keep out of the reach and sight of children.
- For external use only, do not swallow.
- Store between 0°C and 25°C. Do not freeze.
- Discard the bottle 28 days after first opening.
- Consult your doctor, pharmacist or optician before you use AacuLose 0.3% Eye Drops if you are pregnant, breast-feeding or have recently undergone an ophthalmic procedure.
- If you are a contact lens wearer remove your lenses and do not replace them until 30 minutes after using AacuLose 0.3% Eye Drops, Benzalkonium Chloride can be absorbed by lenses and discolour contact lenses.
- If your eye condition persists consult your doctor, pharmacist or optician.
- Dispose of the used bottle according to your local waste management regulations.

9. Pregnancy and Lactation:

Safe use during pregnancy and lactation has not been established.

10. Effects on ability to drive and use machines:

- AacuLose Eye Drops 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

11. Adverse Effects:

- AacuLose Eye Drops rarely causes 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.

12. Over dosage:

- There is no experience of overdose by the ophthalmic route. Overdose is unlikely to occur via the recommended route of administration.

13. Storage Conditions:

- Store between 0°C to 25°C. Protect from light. Do not freeze.



Symbol for "Reference Number"



Symbol for "Sterile"



Symbol for "Batch code"



Symbol for "Manufacturer"



Symbol for "Date of manufacture"



Symbol for "Do not use if package is damaged"



Symbol for "Use Before"



Symbol for "Keep away from sunlight"



Symbol for "Consult instructions for use"



Symbol for "Keep Dry"



European Representative



UK Responsible Person



Distributed by:
TriOn Pharma Ltd - UK
Cowplain PO8 8DL, UK

TriOn Pharma

info@trionpharma.co.uk

UKRP: CMC Medical Devices LTD

Office 32 19-21 Crawford Street, London W1H 1PJ - UK



M/s. Cmc Medical Devices & Drugs S.L.
C/Horacio Lengua 18, CP 29006, Malaga Spain