

**RETAINED CMC LUBRICANT EYE DROPS - carboxymethylcellulose sodium solution
OCuSOFT Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Carboxymethylcellulose sodium 0.5%..... Eye Lubricant

Uses

- Relieves dryness of the eye.
- Temporarily relieves discomfort due to minor irritations of the eye or from exposure to wind or sun.
- As a protectant against further irritation.

Warnings

For use in the eyes only.

Do not use if solution changes color or becomes cloudy.

When using this product

- do not touch tip of container to any surface to avoid contamination.
- do not reuse once opened.

Stop use and ask a doctor if

- you experience eye pain, changes in vision, continued redness or irritation of the eye.
- the condition worsens or persists for more than 72 hours.

KEEP OUT OF THE REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- To open, TWIST AND PULL TAB TO REMOVE.
- Instill 1 or 2 drops into affected eye(s) as needed and discard container.

Other Information

- Use only if printed tamper seals on top and bottom flaps are intact.
- Use only if twist top of single-dose container is intact.
- Store between 15°-30°C (59°-86°F).

Inactive Ingredients

Calcium chloride, magnesium chloride, potassium chloride, purified water, sodium chloride, sodium lactate. May also contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions

Call (800) 233-5469 M-F 8:30AM-5:00PM CST or visit www.retainebrand.com

Purpose

Eye Lubricant

retaine
CMC

retaine
CMC™

DIRECTIONS FOR USE:

- To open, twist and pull tab to remove.
- Instill 1 or 2 drops into affected eye(s) as needed and discard container.

OCuSOFT™
Distributed by OCuSOFT, Inc.
Preserving IX 27471 USA
www.ocusoft.com
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Product of India

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CMC™
LUBRICANT EYE DROPS

Preservative-free

Moisture drops for dry eyes including LASIK dryness

PRESERVATIVE-FREE SENSITIVE FORMULA

Retaine® CMC™ Lubricant Eye Drops provide immediate relief for dry, scratchy, irritated eyes which can be caused by excessive heat, air conditioning, reading, medications or prolonged computer use. The soothing formula utilizes Carboxymethylcellulose (CMC) to restore moisture with the same healthy quality as natural tears and is preservative-free to eliminate the risk of irritation caused by preservatives found in other eye drops.

OCuSOFT™

30 Sterile Single-Dose Containers
0.01 fl oz (0.4 mL) each

Use only if twist top of single-dose container is intact.

Void of Aqueous

0 15718 89730 9

RETAINÉ CMC LUBRICANT EYE DROPS

carboxymethylcellulose sodium solution

Product Information

| | | | | |
|--|---|--|-----------------------------|---------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54799-897 | |
| Route of Administration | OPHTHALMIC | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) (CARBOXYMETHYLCELLULOSE - UNII:05JZI7B19X) | | CARBOXYMETHYLCELLULOSE SODIUM | 5 mg in 1 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| CALCIUM CHLORIDE (UNII: M4I0D6VV5M) | | | | |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) | | | | |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM LACTATE (UNII: TU7HW0W0QT) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:54799-897-30 | 30 in 1 CONTAINER | 09/01/2011 | |
| 1 | | 0.4 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part349 | 09/01/2011 | | |

Labeler - OCuSOFT Inc. (174939207)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|------------------------|
| Altaire Pharmaceuticals, Inc. | | 786790378 | manufacture(54799-897) |