CMC LUBRICANT EYE DROPS- carboxymethylcellulose sodium solution/ drops Amerisource Bergen

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%

Purpose

Lubricant

Uses

- For the temporary relief of burning, irritation and discomfort due to dryness of the eye or exposure to the wind and sun.
- May be used as a protectant against further irritation.

Warnings

- For external use only.
- To avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- If solution changes color or becomes cloudy, do not use.

Stop use and ask a doctor if

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

Keep out of reach of children.

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

Directions

• Instill 1 or 2 drops in the affected eye(s) as needed.

Storage

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Other information

- Do not use if seal on bottle is missing or broken.
- Use before expiration date marked on container.
- Retain this carton for future reference.

Inactive Ingredients:

Purified Water, Boric Acid, Sodium Chloride, Potassium Chloride, Calcium Chloride, Magnesium Chloride. May also contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH;

Preservative:

Chlorine Dioxide 2% solution.

Questions or comments?

1-800-579-8327

Principal Display Panel Text for Container Label:

46122-200-05

Good Neighbor Pharmacy Logo ®

Lubricant

Eye Drops

CMC 0.5% Lubricant Eye Drops

15 mL (0.5 fl oz)

Sterile



Principal Display Panel Text for Carton Label:

46122-200-05

Compare to

Refresh Tears®

active ingredients*

Good Neighbor Pharmacy Logo®

Lubricant

Eye Drops

CMC 0.5%

Lubricant Eye Drops
Moisturizing Drops
for Dry Eyes
15 mL
(0.5 fl oz)



CMC LUBRICANT EYE DROPS

carboxymethylcellulose sodium solution/ drops

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:46122-200 |
| Route of Administration | ОРНТНАЬМІС | | |

| Active Ingredient/Active Moiety | | | |
|---|--------------------------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| Carboxymethylcellulose Sodium (UNII: K679OBS311) (Carboxymethylcellulose - UNII:05JZI7B19X) | Carbo xymethylc ellulo se So dium | 5 mg in 1 mL | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| Water (UNII: 059QF0KO0R) | | |
| Boric Acid (UNII: R57ZHV85D4) | | |
| Sodium Chloride (UNII: 451W47IQ8X) | | |
| Potassium Chloride (UNII: 660 YQ 98 I10) | | |
| Calcium Chloride (UNII: M4I0 D6 VV5M) | | |
| Magnesium Chloride (UNII: 02F3473H9O) | | |
| Hydrochloric Acid (UNII: QTT17582CB) | | |
| Sodium Hydroxide (UNII: 55X04QC32I) | | |
| Chlorine Dioxide (UNII: 8061YMS4RM) | | |

| 1 | Packaging | | | |
|---|------------------|----------------------------|----------------------|--------------------|
| # | ‡ Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:46122-200-05 | 1 in 1 CARTON | | |
| 1 | | 15 mL in 1 BOTTLE, DROPPER | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part349 | 03/22/2013 | |
| | | | |

Labeler - Amerisource Bergen (007914906)

Registrant - Akorn, Inc. (063434679)

| Establishment | | | |
|---------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Akorn, Inc | | 603980319 | MANUFACTURE(46122-200), ANALYSIS(46122-200), STERILIZE(46122-200), PACK(46122-200), LABEL(46122-200) |

Revised: 4/2013 Amerisource Bergen