

MOISTURIZING LUBRICANT- carboxymethylcellulose sodium solution/ drops

Kroger Company

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 feel eye pain.
- changes in vision occur.
- redness or irritation of the eye(s) gets worse, persists or lasts more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1 -800-222-1222).

Directions

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

Other Information

- Use only if imprinted tape seals on top and bottom flaps are intact and clearly legible.
- Use before expiration date marked on container.
- Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
- 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?

1-800-632-6900

Principal Display Panel Text for Container Label:

30142-338-04

Kroger Logo®

STERILE

eye drops

moisturizing

lubricant

CMC 0.5% Lubricant Eyedrops

0.5 FL OZ (15 mL)



Principal Display Panel Text for Carton Label:

COMPARE TO the active Ingredients of

REFRESH TEARS®*See side panel

30142-338-04

Kroger Logo®

FROM OUR FAMILY

TO YOURS

STERILE

eye drops

moisturizing

lubricant

CMC 0.5% Lubricant Eyedrops

Lubricant eye drops
 Moisturizing Drops
 for Dry Eyes
 0.5 FL OZ (15 mL)



MOISTURIZING LUBRICANT

carboxymethylcellulose sodium solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-338
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
Water (UNII: 059QF0KO0R)	
Boric Acid (UNII: R57ZHV85D4)	
Sodium Chloride (UNII: 451W47IQ8X)	
Potassium Chloride (UNII: 660YQ98I10)	
Calcium Chloride (UNII: M4I0D6VV5M)	
Magnesium Chloride (UNII: 02F3473H9O)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Chlorine Dioxide (UNII: 8061YMS4RM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-338-04	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	02/22/2013	

Labeler - Kroger Company (006999528)

Registrant - Akorn, Inc. (063434679)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc		603980319	MANUFACTURE(30142-338) , ANALYSIS(30142-338) , STERILIZE(30142-338) , PACK(30142-338) , LABEL(30142-338)