LEADER LUBRICANT EYE- carboxymethylcellulose sodium solution/ drops
Cardinal Health

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.

Active ingredient Purpose

Carboxymethylcellulose sodium 0.5%..... Eye lubricant

Uses

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

For external use only.

- To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.
- Do not touch unit-dose tip to eye.
- 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 or irritation of the eye, or if the condition worsens or persists for more thatn 72 hours.

Keep out of reach of children. If swallowed get medical help or contact a Poision Control Center right away.

Directions

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

- if used for post-operative (e.g. LASIK) dryness and discomfort, follow your eye doctor's instructions.

Other information

- Use only if single-use container is intact.
- Use before expiration date marked on container.
- Store at 59°-86°F (15°-30°C)
- RETAIN THIS CARTON FOR FUTURE REFERENCE.

Inactive ingredients

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

DISTRIBUTED BY:

CARDINAL HEALTH

DUBLIN, OHIO 43017

LEADER LUBRICANT EYE

carboxymethylcellulose sodium solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49781-032
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)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-032-30	1 in 1 BOX		
1		.04 mL in 1 VIAL, SINGLE-USE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	02/18/2014	

Labeler - Cardinal Health (097537435)

Revised: 2/2014 Cardinal Health