TOPCARE LUBRICATING PLUS- carboxymethylcellulose sodium solution/ drops
Topco Associates LLC

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.

Topco Associates LLC. Lubricating Plus Drug Facts

Active ingredient (in each single-use container)

Carboxymethylcellulose sodium 0.5%

Purpose

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

Warnings

For external use only

Do not use

if solution changes color or becomes cloudy

When using this product

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

Stop use and ask a doctor if

- you experience eye pain
- changes in vision occur
- redness or irritation of the eye continues
- redness or irritation of the eye 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 (1-800-222-1222).

Directions

- to open, twist and pull tab to remove
- instill 1 or 2 drops in the affected eye(s) as needed and discard container

Other information

- store at 20-25°C (68-77°F)
- RETAIN THIS CARTON FOR FUTURE REFERENCE.

Inactive Ingredients

calcium chloride dihydrate, magnesium chloride hexahydrate, potassium chloride, sodium chloride, sodium lactate solution, water for injection. May also contain sodium hydroxide and/or hydrochloric acid to adjust pH.

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

SENSITIVE PRESERVATIVE FREE

Lubricating Plus

Lubricant Eye Drops

CARBOXYMETHYLCELLULOSE SODIUM 0.5%

Moisture drops for dry eyes

Actual Size

COMPARE TO REFRESH PLUS® active ingredient

30 SINGLE-USE CONTAINERS

0.01 FL OZ (0.4 mL) EACH STERILE

TOPCARE LUBRICATING PLUS

carboxymethylcellulose sodium solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-323
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) (CARBOXYMETHYLCELLULOSE - UNII:05JZI7B19X)	CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM	0.5 g in 100 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: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-323-01	14 in 1 CARTON	08/20/2013	12/01/2016
1		5 in 1 POUCH		
1		0.4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
2	NDC:36800-323-65	6 in 1 CARTON	09/04/2013	
2		5 in 1 POUCH		
2		0.4 mL in 1 VIAL, SINGLE-USE; 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	08/20/2013	

Labeler - Topco Associates LLC (006935977)

Revised: 10/2016 Topco Associates LLC