LUBRICATING PLUS- carboxymethylcellulose sodium solution/ drops Major Pharmaceuticals

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.

Major Pharmaceuticals 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 hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions or comments?

1-800-616-2471

Package/Label Principal Display Panel

COMPARE TO the active ingredient of REFRESH PLUS[®] Lubricating PLUS Lubricant Eye Drops Immediate, soothing relief for dry eyes Moisturizing Relief Carboxymethylcellulose Sodium 0.5% 30 Sterile Single-Use Containers 0.01 FL OZ (0.4 mL) each Actual Size



LUBRICATING PLUS									
carboxymethylcellulose sodium so	lution/ drops								
Product Information									
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:0904-6329					
Route of Administration	OPHTHALMIC								
Active Ingredient/Active Moiety									
Ingredient Name			Basis of Strength		Strength				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)			CARBOXYMETHYLCELLULOSE						
(CARBOXYMETHYLCELLULOSE - UNII:05JZI7B19X)		SODIUM			in 100 mL				
T									
Inactive Ingredients									
Ingredient Name			Strength						
CALCIUM CHLORIDE (UNII: M410 D6 V	/V5M)								

MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDRO CHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0904-6329- 46	6 in 1 CARTON	05/09/2013	
1		5 in 1 POUCH		
1		0.4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combinatio Product	n	
	NDC:0904-6329- 51	10 in 1 CARTON	0 5/3 1/20 13	
2		5 in 1 POUCH		
2		0.4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combinatio Product	n	
	NDC:0904-6329- 58	14 in 1 CARTON	0 5/3 1/20 13	10/01/2014
3		5 in 1 POUCH		
3		0.4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combinatio Product	n	
N	Iarketing In	formation		
N	farketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final			05/09/2013	

Labeler - Major Pharmaceuticals (191427277)

Revised: 7/2019

Major Pharmaceuticals