

EYE LUBRICANT - polyethylene glycol, propylene glycol liquid

Kareway Product, Inc.

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 ingredients

Polyethylene Glycol 400 0.4%

Propylene Glycol 0.3%

Purpose

Lubricant

Lubricant

Uses

- for the temporary relief of burning and irritation due to dryness of the eye
- for protection against further irritation

Warnings

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When using this product

- remove contact lenses before using
- do not use if this solution changes color or becomes cloudy
- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eyes lasts
- condition worsens or lasts more than 72 hours

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- Put 1 to 2 drops in the affected eye(s) as needed
- children under 6 years of age: ask a doctor

Other information

Store at 15 - 30°C (59 - 86°F)

Inactive ingredients

benzalkonium chloride, boric acid, hydrochloric acid, hydroxyethyl cellulose, potassium chloride, purified water, sodium chloride, sodium hydroxide

Lubricant Eye Drops Ultra

15mL package
45mm x 92mm x 32mm



EYE LUBRICANT

polyethylene glycol, propylene glycol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0663
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOLS - UNII:3WJQ0SDW1A)	POLYETHYLENE GLYCOL 400	4 mg in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0663-1	1 in 1 BOX		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/11/2012	

Labeler - Kareway Product, Inc. (121840057)