DRY EYE RELIEF- polyethylene glycol and propylene glycol gel Cardinal Health, 110 dba LEADER

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.

Sterile Dry eye Relief

Active Ingredients	Purpose	
Polyethylene Glycol 400 0.4%	Lubricant	
Propylene Glycol 0.3%	Lubricant	

Uses

- for the temporary relief of burning and irritation due to dryness of the eye
- for use as a protectant against further irritation or to relieve dryness of the eye

Warnings

For external use only

Do not use

- if this product changes color or becomes cloudy
- if you are sensitive to any ingredient in this product

When using this product

- 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 experience any of the following:

- you feel eye pain
- changes in vision
- continued redness or irritation of the eye
- condition 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.

Directions

- shake well before using
- put 1 or 2 drops in the affected eye(s) as needed

Other information

store at room temperature

Inactive ingredients

boric acid, edetate disodium, potassium chloride, mangnesium chloride, sodium chloride, sodium borate, purified water. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.





DRY EYE RELIEF

polyethylene glycol and propylene glycol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0088
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII: B697894SGQ)	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	
SODIUM CHLORITE (UNII: G538EBV4VF)		
BORIC ACID (UNII: R57ZHV85D4)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		

MAGNESIUM CHLORATE (UNII: M536P01U3N)	
POTASSIUM CHLORATE (UNII: H35KS68EE7)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:70000- 0088-1	10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/09/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	03/09/2021	

Labeler - Cardinal Health, 110 dba LEADER (063997360)

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