

LEADER LUBRICANT EYE- polyethylene glycol, propylene glycol 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.

Cardinal Health Lubricant Eye Drops Drug Facts

Active ingredients (in each single-use container)

Polyethylene glycol 400 0.4%

Propylene glycol 0.3%

Purpose

Lubricant

Uses

- for the temporary relief of burning and irritation due to 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
- do not reuse
- once opened, discard

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse, persist or lasts 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

- instill 1 or 2 drops in the affected eye(s) as needed

Other information

- store at 20-25°C (68-77°F)
- protect from light

Inactive ingredients

boric acid, calcium chloride dihydrate, hypromellose, magnesium chloride hexahydrate, potassium chloride, sodium chloride, water for injection, zinc chloride. May contain sodium hydroxide and/or hydrochloric acid to adjust pH.

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Sterile

Lubricant Eye Drops

Polyethylene Glycol 0.4%

Propylene Glycol 0.3%

Actual Size

COMPARE TO SYSTANE® active ingredients

Dry Eye Therapy

100% Money Back Guarantee

Long Lasting Relief

Preservative Free

30 STERILE SINGLE-USE VIALS

0.4 mL (0.01 FL OZ) EACH



LEADER LUBRICANT EYE

polyethylene glycol, propylene glycol solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0351
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	0.4 g in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength

BORIC ACID (UNII: R57ZHV85D4)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0K00R)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0351-1	30 in 1 CARTON	04/18/2018	
1		0.4 mL in 1 VIAL; 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	04/18/2018	

Labeler - Cardinal Health (097537435)