LEADER STERILE ULTRA LUBRICATING EYE- polyethylene glycol 400, and 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.

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

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 feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse, persists 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.

Directions

- Shake well before using.
- Instill 1 or 2 drops in the affected eye(s) as needed.

Other information

- Store at room temperature

Inactive ingredients

boric acid, calcium chloride, chlorhexidine gluconate (20%), hydrochloric acid, hypromellose 2910, magnesium chloride, potassium chloride, purified water, sodium chloride, sodium hydroxide, zinc chloride

Distributed by:

Cardinal Health

Dublin, Ohio 43017

www.myleader.com

1-800-200-6313

LEADER STERILE ULTRA LUBRICATING EYE

polyethylene glycol 400, and propylene glycol solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0101
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	400 mg in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ZINC CHLORIDE (UNII: 86Q357L16B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0101-1	1 in 1 BOX		
1		15 mL in 1 PACKAGE; 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	03/18/2016	

Labeler - Cardinal Health (097537435)

Revised: 3/2016 Cardinal Health