LEADER LUBRICANT EYE DROPS - polyethylene glycol 400 solution
HANLIM PHARM. CO., LTD.

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----------Purpose

Polyethylene Glycol 400 (0.4%)----------Lubricant

Propylene Glycol (0.3%)----------Lubricant

Uses

For the temporary relief of burning and irritation due to eye dryness.

Warnings

For external use only.

Do not use
- if solution changes color or becomes cloudy
- if you are sensitive or allergic to any ingredient in this product

When using this product
- to avoid contamination, do not touch tip of container to any surface
- replace cap after each use

Stop use and ask a doctor if
- you experience eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse or lasts more than 72 hours

Keep out of reach of children.

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

Directions
- Put 1 or 2 drops in the affected eye/s as needed.

Inactive ingredients: Boric Acid, Calcium Chloride, Chlorhexidine Gluconate, Hydrochloric Acid, Hydroxypropyl Guar,

Magnesium Chloride, Potassium Chloride, Purified Water, Sodium Chloride, Zinc Chloride

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LEADER LUBRICANT EYE DROPS

polyethylene glycol 400 solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11716-1192
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL - UNII:3WJQ0SDW1A)	POLYETHYLENE GLYCOL 400	0.4 mL in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	0.3 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BORIC ACID (UNII: R57ZHV85D4)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CHLORIDE (UNII: 86Q357L16B)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11716-1192-6	1 in 1 CARTON		
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	04/28/2010	

Labeler - HANLIM PHARM. CO., LTD. (687986034)

Revised: 4/2010 HANLIM PHARM. CO., LTD.