QUALITY CHOICE LUBRICANT EYE - polyethylene glycol 400, propylene glycol solution/drops

CHAIN DRUG MARKETING ASSOCIATION 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 Purpose

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

Propylene Glycol (0.3%)....Lubricant

Uses

For the relief of burning, irritation due to dryness of the eye.

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.

Other information

- some users may experience a brief tingling sensation
- Store at room temperature

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

 $Magnesium\,Chloride,\,Purified\,Water,\,Sodium\,Chloride,\,Zinc\,\,Chloride$

Distributed by C.D.M.A., Inc.

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

Made in Korea



QUALITY CHOICE LUBRICANT EYE

polyethylene glycol 400, propylene glycol solution/ drops

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-968		
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		
BORIC ACID (UNII: R57ZHV85D4)			
CALCIUM CHLO RIDE (UNII: M4I0 D6 VV5M)			
CHLORHEXIDINE GLUCONATE (UNII: MOR8 4MUD8 E)			
HYDRO CHLO RIC ACID (UNII: QTT17582CB)			
MAGNESIUM CHLO RIDE (UNII: 02F3473H9O)			
POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
ZINC CHLORIDE (UNII: 86Q357L16B)			
WATER (UNII: 059QF0KO0R)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63868-968-15	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	09/30/2012			

Labeler - CHAIN DRUG MARKET ING ASSOCIATION INC (011920774)

Revised: 9/2012 CHAIN DRUG MARKETING ASSOCIATION INC