

QUALITY CHOICE LUBRICANT TEARS EYE - glycerin, hypromellose, polyethylene glycol 400 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
Glycerin 0.2%.....	Lubricant
Hypromellose 0.2%.....	Lubricant
Polyethylene glycol 400 1%.....	Lubricant

Uses

- for the temporary relief of burning and irritation due to dryness of the eye
- for protection against further irritation

Warnings

For external use only.

Do not use:

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

When using this product

- remove contact lenses before use
- do not use if this solution changes color or becomes cloudy
- 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 lasts
- condition worsens or lasts more than 72 hours

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Instill 1 or 2 drops in the affected eye(s) as needed.
- children under 6 years of age: ask a doctor

Other information

- some users may experience a brief tingling sensation
- store at 15° to 25°C (59° to 77°F)

Inactive ingredients

benzalkonium chloride, boric acid, dextrose, glycine, magnesium chloride, potassium chloride, purified water, sodium borate, sodium chloride, sodium citrate, sodium lactate.

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

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Made in Korea



QUALITY CHOICE LUBRICANT TEARS EYE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-967
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2 mg in 1 mL
HYPROMELLOSES (UNII: 3NXW29V3WO) (HYPROMELLOSES - UNII:3NXW29V3WO)	HYPROMELLOSES	2 mg in 1 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-967-15	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)

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