

TOPCARE HEALTH LUBRICANT EYE DROPS- polyethylene glycol 400, propylene glycol solution

Topco Assoc LLC

Topcare Health Lubricant Eye Drops (PLD)

Active ingredients

Polyethylene glycol 400 0.4%

Propylene glycol 0.3%

Purpose

Polyethylene glycol 400.....Lubricant

Propylene glycol.....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 the 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 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

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

Other information

- **RETAIN THIS CARTON FOR FUTURE REFERENCE**
- Store at room temperature

Inactive ingredients

Benzalkonium chloride as preservative, boric acid, calcium chloride, hypromellose, magnesium chloride, potassium chloride, purified water, sodium borate, sodium chloride,



TopCare health
Eye Drops
Lubricant

Drug Facts

Active Ingredients	Purpose
Polyethylene glycol 400 0.4%	Lubricant
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*This product is not manufactured or distributed by Alcon Laboratories, Inc., distributor of Systane® Lubricant Eye Drops.

Drug Facts
(continued)

Directions

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TopCare health™

COMPARE TO SYSTANE® LUBRICANT EYE DROPS ACTIVE INGREDIENTS*

Lubricant

Eye Drops

Long Lasting Relief
Soothing Comfort
Dry Eye Therapy

Sterile

0.5 FL OZ (15 mL)

LOT
EXP

Tamper Evident. Do not use this product if imprinted neckband on bottle is broken or missing.

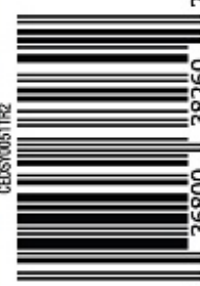
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✓ **QUALITY GUARANTEED**

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



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CE05Y005 T102

polyethylene glycol 400, propylene glycol solution

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-978
Route of Administration	OPHTHALMIC		

Ingredient Name	Basis of Strength	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	0.3 g in 100 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	0.4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-978-01	1 in 1 CARTON	02/07/2020	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	02/07/2020	

Labeler - Topco Assoc LLC (006935977)

Registrant - K.C. Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
K.C. Pharmaceuticals, Inc.		174450460	manufacture(36800-978) , pack(36800-978) , label(36800-978)

Revised: 12/2023

Topco Assoc LLC