

TOPCARE HEALTH DRY EYE RELIEF EYE DROPS- glycerin, hypromellose, polyethylene glycol 400 solution
Topco Associates LLC

Topcare Health Dry Eye (PLD)

Active ingredients

Glycerin 0.2%

Hypromellose 0.2%

Polyethylene glycol 4001%

Purposes

Glycerin.....Lubricant

Hypromellose.....Lubricant

Polyethylene glycol 400.....Lubricant

Uses

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

Warnings

For external use only

Do not use this product if solution changes color or becomes cloudy

When using this product

- to avoid contamination, do not touch tip of container to any surface. Replace cap after using.

Stop use and ask a doctor if you experience

- eye pain
- changes in vision
- continued redness or irritation of the eye, or if the condition worsens or persists for 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 (1-800-222-1222),

right away.

Directions

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

Other information

store at 15°-30°C (59°-86°F)

Inactive ingredients

benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate dibasic, sodium phosphate monobasic

The image displays the packaging for TopCare Health Dry Eye Relief Eye Drops. The layout includes the front panel, back panel, and side panel.

Front Panel: Features the TopCare Health logo, the product name "Dry Eye Relief Eye Drops", and the volume "0.5 FL OZ (15 mL)". It also includes a "Sterile" label and a "Compare to Visine® Dry Eye Relief Active Ingredients*" claim. A QR code is present for more information.

Back Panel: Contains detailed "Drug Facts" (continued), "Other information" (storage), "Inactive ingredients", "Uses", "Warnings", "When using this product", "Stop use and ask a doctor if you experience", "If pregnant or breast-feeding", "Keep out of reach of children", and "Directions".

Side Panel: Includes distribution information, a "Quality Guaranteed" seal, and a barcode.

Drug Facts (continued):

Active ingredients	Purposes
Glycerin 0.2%	Lubricant
Hypromellose 0.2%	Lubricant
Polyethylene glycol 400 1%	Lubricant

Other information: store at 15°-30°C (59°-86°F)

Inactive ingredients: benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate dibasic, sodium phosphate monobasic

Uses: ■ for protection against further irritation
■ for temporary relief of burning and irritation due to dryness of the eye

Warnings: For external use only
Do not use this product if solution changes color or becomes cloudy

When using this product: ■ to avoid contamination, do not touch tip of container to any surface. Replace cap after using.
■ remove contact lenses before using

Stop use and ask a doctor if you experience: ■ eye pain ■ changes in vision
■ continued redness or irritation of the eye, or if the condition worsens or persists for 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 (1-800-222-1222) right away.

Directions: ■ instill 1 to 2 drops in the affected eye(s) as needed
■ children under 6 years of age: ask a doctor

DISTRIBUTED BY: TOPCO ASSOCIATES LLC
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TOPCARE HEALTH DRY EYE RELIEF EYE DROPS

glycerin, hypromellose, polyethylene glycol 400 solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-845
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	1 g in 100 mL
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) (HYPROMELLOSE, UNSPECIFIED - UNII:3NXW29V3WO)	HYPROMELLOSE, UNSPECIFIED	0.2 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
DEXTROSE (UNII: IY9XDZ35W2)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-845-01	1 in 1 CARTON	02/06/2020	
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	02/06/2020	

Labeler - Topco Associates LLC (006935977)

Establishment			
Name	Address	ID/FEI	Business Operations
K.C. Pharmaceuticals, Inc.		174450460	pack(36800-845) , label(36800-845) , manufacture(36800-845)

Revised: 12/2023

Topco Associates LLC