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

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.

Topcare Health Dry Eye/PLD

Active ingredients

Glycerin 0.2%

Hypromellose 0.2%

Polyethylene glycol 400 .....1%

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

TOPCARE HEALTH DRY EYE RELIEF EYE DROPS

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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
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.2 g in 100 mL
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

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
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)	

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 final	part349	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: 2/2020 Topco Associates LLC