DRY EYE RELIEF- glycerin, hypromellose, polyethylene glycol liquid
Strategic Sourcing Services 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.

DRUG FACTS

Active ingredients

Glycerin 0.2%

Hypromellose 0.2%

Polyethylene glycol 1%

Purpose

Glycerin.....Lubricant

Hypromellose.....Lubricant

Polyethylene glycol 400.....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 this product if solution changes color or becomes cloudy

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

When using this product

- to avoid contamination, do not touch tip of container to any surface
- replace cap after using. Keep container tightly closed
- remove contact lens before using

Keep out of reach of children

If accidentally swallowed get medical help or contact a Poison Control Center immediately

If pregnant and breast-feeding, ask a health professional before use

Directions

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

Other information

RETAIN THIS CARTON FOR FUTURE REFERENCE

Store at 15 ^{o}C-30 ^{o}C (59 ^{o}-86 ^{o}F)

Inactive ingredients

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

DRY EYE RELIEF

glycerin, hypromellose, polyethylene glycol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49348-095
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO) (HYPROMELLOSE, UNSPECIFIED - UNII:3NXW29V3WO)	HYPROMELLOSES	0.2 g in 100 mL
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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-095-29	1 in 1 CARTON	05/01/2013	
1		15 mL in 1 BOTTLE, PLASTIC; 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	05/01/2013	

Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(49348-095) , pack(49348-095) , label(49348-095)

Revised: 10/2019 Strategic Sourcing Services LLC