

LEADER DRY EYE RELIEF EYE DROPS- glycerin, hypromellose, polyethylene glycol 400 solution/ drops
Cardinal Health

Leader Dry Eye Relief Eye Drops 15mL and 15mL twin pk (PLD)

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

When using this product

- to avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- remove contact lens 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 or 2 drops in the affected eye(s) as needed

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

Leader Dry Eye Relief Eye Drops 15mL



Leader Dry Eye Relief Eye Drops 15mL twin pk



LEADER DRY EYE RELIEF EYE DROPS

glycerin, hypromellose, polyethylene glycol 400 solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0502
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

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) (HYPROMELLOSE, UNSPECIFIED - UNII:3NXW29V3WO)	HYPROMELLOSE, UNSPECIFIED	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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
DEXTROSE (UNII: IY9XDZ35W2)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0502-1	1 in 1 CARTON	04/30/2019	
1		15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:70000-0502-2	2 in 1 CARTON	04/30/2019	
2		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 Drug	M018	04/30/2019	

Labeler - Cardinal Health (063997360)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(70000-0502) , pack(70000-0502) , label(70000-0502)