LEADER PRESERVATIVE-FREE ULTRA LUBRICATING EYE DROPS- polyethylene glycol 400, propylene glycol solution/ drops
Cardinal Health

Leader Preservative-Free Ultra Lubricating 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 of the eye 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
• do not reuse
• once opened, discard

Stop use and ask a doctor if
• you feel eye pain
• changes in vision occur
• redness or irritation of the eye(s) gets worse, persists or lasts 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°-25°C (59°-77°F)
- use only if single-use container is intact
- use before expiration date marked on container
- **RETAIN THIS CARTON FOR FUTURE REFERENCE**

Inactive ingredients

boric acid, hypromellose, potassium chloride, purified water, sodium chloride. May

contain sodium hydroxide and/or hydrochloric acid to adjust pH.

Questions or comments? Call 1-888-527-4276

LEADER PRESERVATIVE-FREE ULTRA LUBRICATING EYE DROPS

polyethylene glycol 400, propylene glycol solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0501
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	0.4 g in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	

WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0501-1	25 in 1 BOX	04/30/2019	
1		0.4 mL in 1 VIAL, SINGLE-USE; 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	pack(70000-0501) , label(70000-0501)

Establishment

Name	Address	ID/FEI	Business Operations
Unimed		689852052	manufacture(70000-0501)

Revised: 9/2024 Cardinal Health