

**LEADER LUBRICANT EYE DROPS 30CT- polyethylene glycol 400, propylene glycol liquid
KC Pharmaceuticals, Inc.**

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.

Leader Lubricant Eye Drops 30ct

Active ingredients

Polyethylene glycol 400 0.4%

Propylene glycol 0.3%

Purposes

Lubricant

Lubricant

Use

- 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 the solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product

When using this product

- do not touch 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 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

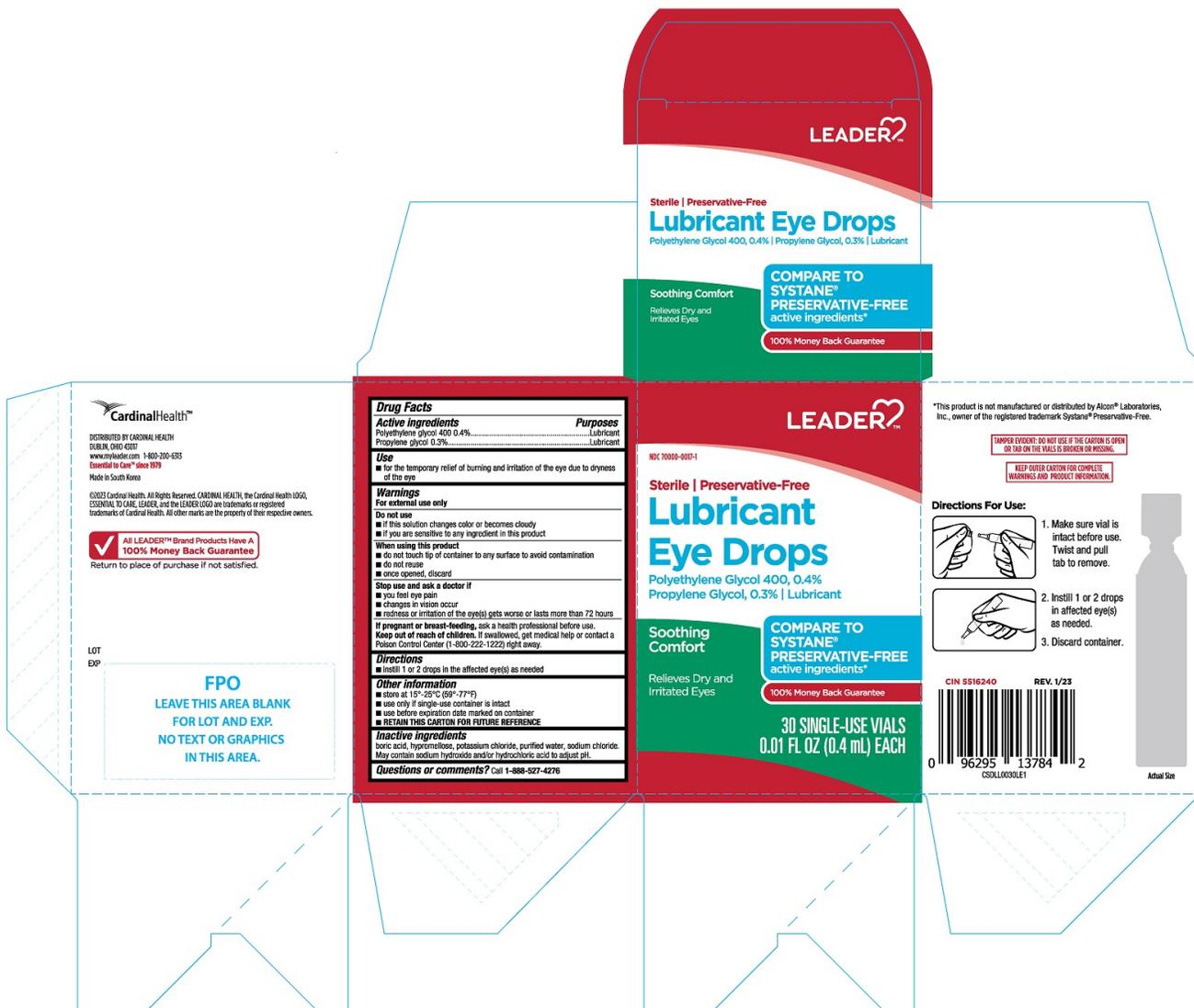
- store at 15°-25°C (59°-77°F)
- use only if single-use container is intact
- use before expiration date marked on container
- RETAIN THIS CARTON FOR FUTURE REFERENCE

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 LUBRICANT EYE DROPS 30CT

polyethylene glycol 400, propylene glycol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55651-017
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ) (POLYETHYLENE GLYCOL, UNSPECIFIED - UNII:3WJQOSDW1A)	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
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
BORIC ACID (UNII: R57ZHV85D4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55651-017-01	30 in 1 BOX	07/18/2019	
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 final	part349	07/18/2019	

Labeler - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
K.C. Pharmaceuticals, Inc.		174450460	pack(55651-017) , label(55651-017)

Establishment

Name	Address	ID/FEI	Business Operations
Unimed		689852052	manufacture(55651-017)

Revised: 2/2023

KC Pharmaceuticals, Inc.