

LEADER ULTRA LUBRICATING EYE DROPS- polyethylene glycol, propylene glycol liquid
Cardinal Health

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.

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 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
- replace cap after each use

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

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
- Children under 6 years of age: ask a doctor

Other information

- RETAIN THIS CARTON FOR FUTURE REFERENCE
- Store at room temperature

Inactive ingredients

Aminomethylpropanol, benzalkonium chloride as preservative, boric acid, hypromellose, potassium chloride, purified water, sodium chloride, sorbitol

Ultra Lubricating Eye Drops

Sterile | High Performance

LEADER™

Drug Facts

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Drug Facts (continued)

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Questions or comments?

1-888-527-4276

*This product is not manufactured or distributed by Alcon Laboratories, Inc., owner of the registered trademark Systane® Ultra Lubricant Eye Drops.

100% Money Back Guarantee
Return to place of purchase if not satisfied.

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF IMPRINTED NECKBAND ON BOTTLE IS BROKEN OR MISSING.

LEADER™

NDC 70000-0457-1

Sterile | High Performance

Ultra Lubricating Eye Drops

Polyethylene Glycol 400, 0.4%
Propylene Glycol, 0.3%
Lubricant

Relieves Dry
and Irritated
Eyes

**COMPARE TO
SYSTANE® ULTRA
LUBRICANT
EYE DROPS
active ingredients***

**100% Money
Back Guarantee**

0.5 fl oz (15 mL)

CardinalHealth™

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DUBLIN, OHIO 43017
www.myleader.com
1-800-200-6303
Essential to Care™ since 1979

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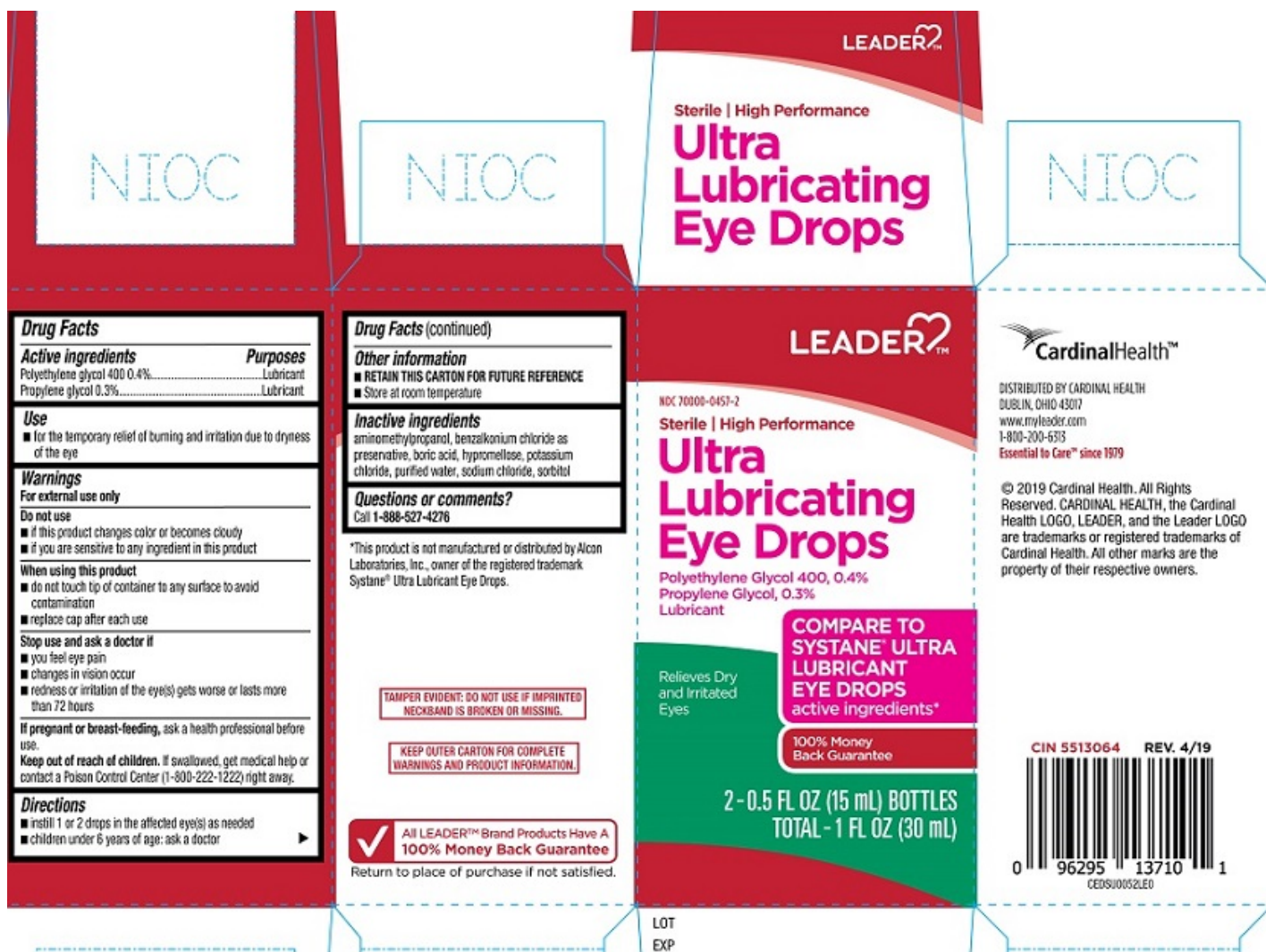
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FOR LOT AND EXP.
NO TEXT OR GRAPHICS
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LEADER ULTRA LUBRICATING EYE DROPS

polyethylene glycol, propylene glycol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0457
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
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

BORIC ACID (UNII: R57ZHV85D4)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
POTASSIUM CHLORIDE (UNII: 660YQ98H0)				
WATER (UNII: 059QF0KO0R)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SORBITOL (UNII: 506T60A25R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0457-1	1 in 1 BOX	02/19/2019	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:70000-0457-2	2 in 1 BOX	04/30/2019	
2		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	02/19/2019	

Labeler - Cardinal Health (097537435)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(70000-0457) , pack(70000-0457) , label(70000-0457)