

LUBRICATING RELIEF- polyethylene glycol 400 and propylene glycol solution/ drops
Kroger Company

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

Polyethylene Glycol 400 0.4%

Propylene Glycol 0.3%

Purpose

Lubricant

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 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, persists or lasts more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1 -800-222-1222).

Directions

- Shake well before using.
- Instill 1 or 2 drops in the affected eye(s) as needed.

Other Information

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Inactive Ingredients:

Purified Water, Sorbitol solution, Boric Acid, 2-amino-2-methyl-1-propanol, Hypromellose USP, Sodium Chloride, Potassium Chloride. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH;

Preservative: Benzalkonium Chloride.

Questions or comments?

1-800-632-6900

Principal Display Panel Text for Container Label:

30142-327-04

Kroger Logo® STERILE

eye drops

lubricating relief

Polyethylene Glycol 400 0.4%/Propylene Glycol 0.3%

10 mL (0.3 FL OZ)



Principal Display Panel Text for Carton Label:

COMPARE TO the active Ingredients of

SYSTANE ULTRA®*See side panel

30142-327-04

Kroger Logo®

FROM OUR FAMILY

TO YOURS

STERILE

eye drops

lubricating

relief

Polyethylene Glycol 400 0.4%

Propylene Glycol 0.3%

Lubricant eye drops

for irritated eyes

- Long-Lasting Protection
- Fast Relief

0.3 FL OZ (10 mL)



LUBRICATING RELIEF

polyethylene glycol 400 and propylene glycol solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-327
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	4 mg in 1 mL
Propylene Glycol (UNII: 6DC9Q167V3) (Propylene Glycol - UNII:6DC9Q167V3)	Propylene Glycol	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Sorbitol (UNII: 506T60A25R)	
Boric Acid (UNII: R57ZHV85D4)	
Aminomethylpropanol (UNII: LU49E6626Q)	
Hypromelloses (UNII: 3NXW29V3WO)	
Sodium Chloride (UNII: 451W47IQ8X)	
Potassium Chloride (UNII: 660YQ98I10)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Benzalkonium Chloride (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-327-04	1 in 1 CARTON		
1		10 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	02/22/2013	

Labeler - Kroger Company (006999528)**Registrant** - Akorn, Inc. (062649876)**Establishment**

Name	Address	ID/FEI	Business Operations
Akorn, Inc		603980319	MANUFACTURE(30 142-327) , ANALYSIS(30 142-327) , STERILIZE(30 142-327) , PACK(30 142-327) , LABEL(30 142-327)