

LUBRICANT EYE DROPS SOLUTION- polyethylene glycol 400 and propylene glycol solution
AvPAK

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.

Lubricant Eye Drops Solution

<i>Active Ingredients</i>	<i>Purpose</i>
Polyethylene Glycol 400 0.4%	Lubricant
Propylene Glycol 0.3%	Lubricant

Uses

- For the temporary relief of burning, irritation and discomfort due to dryness of the eye and exposure to wind or sun.
- May be used as a protectant against further irritation.

Warnings

For use in the eyes only

Do not use

- If solution changes color or becomes cloudy.

When using this product

- avoid contamination, do not touch tip of container to any surface
- replace cap after use

Stop use and ask a doctor if

- you experience eye pain, changes in vision, continued redness or irritation of the eye
- the condition worsens or persists for more than 72 hours

Keep this and all drugs out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Directions

- shake well before use
- instill 1 or 2 drops in the affected eye(s) as needed

Other Information

- store at room temperature 15°- 30°C (59°-86°F).
- do not use if imprinted seal on cap is torn, broken or missing
- discard 90 days after opening
- retain outer carton for full product information

Inactive Ingredients:

Benzalkonium chloride (preservative), boric acid, calcium chloride, hypromellose, magnesium chloride, potassium chloride, purified water, sodium chloride, zinc chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions?

1-855-361-3993

Distributed by:

AvKARE

Pulaski, TN 38478

www.avkare.com

Rev. 12/2022 AV 12/2022

PRINCIPAL DISPLAY PANEL

AVKARE
NDC 50268-126-15
Lubricant Eye Drops Solution
Polyethylene Glycol 400 0.4% /
Propylene Glycol 0.3%
(Eye Lubricants)
Lubricant Eye Drops
STERILE
0.5 FL OZ (15 mL)

DO NOT USE IF TAMPER EVIDENT SEAL IS TORN, BROKEN OR MISSING

Drug Facts
Active ingredient Purpose
Polyethylene Glycol 400 0.4% Eye Lubricant
Propylene Glycol 0.3% Eye Lubricant
Use: • For the temporary relief of burning, irritation and discomfort due to dryness of the eye or exposure to wind or sun. May be used as a protectant against further irritation.
Warnings: For use in the eyes only
Keep this and all drugs out of the reach of children.
Directions: Instill 1 or 2 drops in the affected eye(s) as needed.
Other information: DO NOT USE IF IMPRINTED SEAL ON CAP IS TORN, BROKEN OR MISSING.
• Retain outer carton for full product information.
Inactive ingredients: See outer carton.
Questions? 1-855-361-3993
Distributed by: AvKARE, Pulaski, TN 38478
Rev. 12/2022 AV 12/2022

LUBRICANT EYE DROPS SOLUTION

polyethylene glycol 400 and propylene glycol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50268-126
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
BORIC ACID (UNII: R57ZHV85D4)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-126-15	1 in 1 CARTON	02/25/2003	
1		15 mL in 1 BOTTLE; 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	02/25/2003	

Labeler - AvPAK (832926666)