ARTIFICIAL TEARS LUBRICANT EYE- polyvinyl alcohol and povidone liquid Prestige Brands Holdings, 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.

Artificial Tears Lubricant Eye Drops

Drug Facts

Active ingredients

Polyvinyl alcohol 0.5%

Povidone 0.6%

Purpose

Lubricant

Uses

- For the temporary relief of burning & irritations due to dryness of the eye.
- For use as a protectant against further irritation or to relieve dryness of the eye.

Warnings

For external use only

Do not use if

solution changes color or becomes cloudy.

When using this product:

- to avoid contamination, do not touch tip to any surface.
- replace cap after using.

Stop use and ask a doctor if:

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Instill 1 to 2 drops in the affected eye(s) as needed.

Other information

- Store at room temperature
- Remove contact lenses before using

Inactive ingredients

benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate (mono- and dibasic)

Questions?

1-877-274-1787

PRINCIPAL DISPLAY PANEL

Sterile
Artificial Tears
Lubricant Eye Drops
0.5 FL OZ (15 mL)



ARTIFICIAL TEARS LUBRICANT EYE

polyvinyl alcohol and povidone liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-181
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990)	POLYVINYL ALCOHOL, UNS PECIFIED	5.0 mg in 1 mL	
PO VIDO NE (UNII: FZ989GH94E) (PO VIDO NE - UNII: FZ989GH94E)	POVIDONE	6.0 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)		
DEXTROSE (UNII: IY9 XDZ35W2)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)		
WATER (UNII: 059QF0KO0R)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)		
SODIUM PHO SPHATE, MO NO BASIC (UNII: 3980 JIH2SW)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:67172-181- 01	1 in 1 BOX	06/01/2012	
l	1	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

l	Marketing Inform	nation		
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC MONOGRAPH FINAL	part349	06/01/2012	

Labeler - Prestige Brands Holdings, Inc. (159655021)

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