

TOPCARE HEALTH ARTIFICIAL TEARS- polyvinyl alcohol, povidone solution
Topco Associates LLC

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.

Topcare Artificial Tears PLD

Active ingredients

Polyvinyl alcohol 0.5%

Povidone 0.6%

Purpose

Polyvinyl alcohol.....Eye lubricant

Povidone.....Eye lubricant

Uses

- for use as a protectant against further irritation or to relieve dryness of the eye
- for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun

Warnings

For external use only

Do not use this product if solution changes color or becomes cloudy

Stop use and ask a doctor if you experience

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

When using this product

- to avoid contamination, do not touch tip of container to any surface
- replace cap after using. Keep container tightly closed
- remove contact lens before using

Keep out of the reach of children. If accidentally swallowed, get medical help or contact a Poison Control Center immediately

Directions

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

Other information

- Tamper Evident. Do not use this product if imprinted neckband is missing or broken.
- **RETAIN THIS CARTON FOR FUTURE REFERENCE**
- **Store at 15°-30° C (59°-86° F)**

Inactive ingredients

benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate dibasic, and sodium phosphate monobasic



TOPCARE HEALTH ARTIFICIAL TEARS

polyvinyl alcohol, povidone solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-972
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	0.6 g in 100 mL
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990)	POLYVINYL ALCOHOL, UNSPECIFIED	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE (UNII: IY9XDZ35W2)	

SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0K00R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-972-01	1 in 1 CARTON	01/31/2020	
1		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	01/31/2020	

Labeler - Topco Associates LLC (006935977)

Registrant - K.C. Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
K.C. Pharmaceuticals, Inc.		174450460	manufacture(36800-972) , pack(36800-972) , label(36800-972)

Revised: 2/2020

Topco Associates LLC