FAMILY CARE ARTIFICIAL EYE- polyvinyl alcohol, and povidones solution/ drops
United Exchange Corp.

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 **Purpose**

Polyvinyl alcohol 0.5%.....Lubricant

Povidone 0.6%.....Lubricant

Uses

- For the temporary relief of burning & irritation 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 or 2 drops in the affected eye(s) as needed.

Other information

- store at room temperature
- remove contact lenses before using

Inactive ingredients

benzalkonium chloride, dibasic sodium phosphate hydrate, edetate disodium, glucose, hydrochloric acid, monobasic sodium phosphate, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate hydrate, sodium hydroxide

Distributed by:

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Made in Korea

FAMILY CARE ARTIFICIAL EYE

polyvinyl alcohol, and povidones solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65923-512

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, UNSPECIFIED	.05 mg in 1 mL
POVIDONES (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONES	.06 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC DIHYDRATE (UNII: 94255I6E2T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-512-15	1 in 1 BOX	04/27/2016	
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	04/22/2016	

Labeler - United Exchange Corp. (840130579)

Revised: 4/2016 United Exchange Corp.