FAMILY CARE ADVANCED FORMULA EYE- tetrahydrozoline hydrochloride, dextran 70, polyethylene glycol 400, povidone 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.

Family Care Eye Drops Advanced Formula 0.5oz 511A DW (2020)

Povidone 1%.....Lubricant

Uses

- for the relief of redness of the eyes due to minor eye irritations
- for use as a protectant against further irritation or to relieve dryness of the eye

Warnings

For external use only

Ask a doctor before use if you have narrow angle glaucoma.

When using this product

- pupils may become enlarged temporarily
- overuse may cause more eye redness
- remove contact lenses before using
- do not use if this solution changes color or becomes cloudy
- to avoid contamination, do not touch tip of container to any surface
- 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 persists
- condition worsens or lasts more than 72 hours

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

- to open bottle, push cap down and twist counter-clockwise
- put 1 to 2 drops in the affected eye(s) up to 4 times daily
- children under 6 years of age: ask a doctor

Other information

• store at 15° to 25°C (59° to 77°F)

Inactive ingredients: benzalkonium chloride, boric acid, edetate disodium, purified water, sodium chloride, and sodium borate

Distributed by:

United Exchange Corp.
Cypress, CA 90630 USA

Made in South Korea



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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-511	
Route of Administration	OPHTHALMIC			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
TETRAHYDRO ZOLINE HYDRO CHLO RIDE (UNII: 0 YZT43HS7D) (TETRAHYDRO ZOLINE - UNII:S9 U0 25 Y0 77)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL			
DEXTRAN 70 (UNII: 7SA290 YK68) (DEXTRAN 70 - UNII:7SA290 YK68)	DEXTRAN 70	1 mg in 1 mL			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	10 mg in 1 mL			
PO VIDO NE (UNII: FZ989GH94E) (PO VIDO NE - UNII: FZ989GH94E)	POVIDONE	10 mg in 1 mL			

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			
BORIC ACID (UNII: R57ZHV85D4)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
WATER (UNII: 059QF0KO0R)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM BORATE (UNII: 91MBZ8H3QO)			

I	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65923-511-15	1 in 1 CARTON	11/25/2014		
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	11/25/2014		

Labeler - United Exchange Corp (840130579)

Revised: 2/2020 United Exchange Corp