

ADVANCE RELIEF EYE DROPS- dextran 70, polyethylene glycol 400, povidone, tetrahydrozoline hcl solution/ drops

WinCo Foods, 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.

Winco Advanced Relief Eye Drops-PLD

☐Active ingredients

Dextran 70 0.1%

Polyethylene glycol 400 1%

Povidone 1%

Tetrahydrozoline HCl 0.05%

☐Purpose

Dextran 70...Lubricant

Polyethylene glycol 400...Lubricant

Povidone...Lubricant

Tetrahydrozoline HCl...Redness Reliever

Uses

- relieves redness of the eye due to minor eye irritations
- as a lubricant to prevent 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
- to avoid contamination, do not touch tip of container to any surface. Replace cap after using
- if solution changes color or becomes cloudy, do not use
- overuse may produce increased redness of the eye
- remove contact lens before using

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

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

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) up to four times daily.

Other information

- Store at 15°-30°C (59°-86°F)

Inactive ingredients

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



ADVANCE RELIEF EYE DROPS

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-282
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTRAN 70 (UNII: 7SA290YK68) (DEXTRAN 70 - UNII:7SA290YK68)	DEXTRAN 70	100 mg in 100 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	1000 mg in 100 mL
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	1000 mg in 100 mL
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	50 mg in 100 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-282-15	1 in 1 BOX	01/09/2015	
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	01/09/2015	

Labeler - WinCo Foods, LLC (056098817)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(67091-282) , label(67091-282) , pack(67091-282)