

PREMIER VALUE STERILE EYE DROPS- dextran 70 polyethylene glycol 400 povidone tetrahydrozoline hci solution/ drops
Chain Drug Consortium, 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.

Active Ingredients	Purpose
Dextran 70 0.1%.....	Lubricant
Polyethylene glycol 400 1%.....	Lubricant
Povidone 1%.....	Lubricant
Tetrahydrozoline HCl 0.05%.....	Redness Reliever

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

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 for 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

- 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






- some users may experience a brief tingling sensation
- store at 15° to 25°C (59° to 77°F)

Inactive ingredients

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

DISTRIBUTED BY:

CHAIN DRUG CONSORTIUM
 3301 NW BOCA RATON BLVD
 SUITE 101, BOCA RATON, FL 33431 USA

-  **Bleed**
-  **Dieline**
-  **Folded line**
-  **Live area**
-  **Glue flap/No ink/No varnish**



PREMIER VALUE STERILE EYE DROPS

dextran 70 polyethylene glycol 400 povidone tetrahydrozoline hci solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-449
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTRAN 70 (UNII: 7SA290YK68) (DEXTRAN 70 - UNII:7SA290YK68)	DEXTRAN 70	.001 mg in 1 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	.01 mg in 1 mL
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	.01 mg in 1 mL
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	.0005 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0K00R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORATE (UNII: T95DR77GMR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-449-00	1 in 1 BOX		
1		15 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/23/2014	

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 1/2014

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