PREMIER VALUE ORIGINAL- tetrahydrozoline hydrochloride 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 Ingredient Purpose

Tetrahydrozoline HCl 0.05%..... Redness Reliever

Use

- for the relief of redness of the eyes due to minor eye irritations

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 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 Poision Control Center right away.

Directions

- To open bottle, push cap down and twist counterclockwise. To close bottle, twist clockwise until it stops turning
- Put 1 to 2 drops in the affected eye(s) up to 4 times daily.

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

PREMIER VALUE ORIGINAL

tetrahydrozoline hydrochloride solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-448
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 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:68016-448-00	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	01/27/2014	

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 1/2015 Chain Drug Consortium, LLC