PREMIER VALUE ORIGINAL- tetrahydrozoline hydrochloride solution
HANLIM PHARM. CO., LTD.

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.

DRUG FACTS

Active ingredient Purpose

Tetrahydrozoline HCL 0.05%.....Redness Reliever

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

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 become cloudy
- do not touch tip of container to any surface to avoid contamination
- 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 lasts
- 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
- 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 15º to 25ºC (59º to 77ºF)

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

Distributed By:

Chain Drug Consortium, LLC.

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PREMIER VALUE ORIGINAL

tetrahydrozoline hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11716-0101
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 CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11716-0101-1	1 in 1 CARTON		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	05/19/2014	

Labeler - HANLIM PHARM. CO., LTD. (687986034)

Revised: 5/2014 HANLIM PHARM. CO., LTD.