PREMIER VALUE EYE AC - tetrahydrozoline hydrochloride and zinc sulfate 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 Ingredients — Purpose

Tetrahydrozoline HCL 0.05% .....Redness Reliever

Zinc Sulfate 0.25% .....Astringent

Uses

- for the temporary relief of redness and irritation of the eye and for use as a protectant against further irritation.
- for the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun.

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 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

- Instill 1 or 2 drops in the affected eye(s) up to 4 times daily
- Store at 15^{o} to 25^{o}C (59^{o} to 77^{o}F)
- Children under 6 years of age: Ask a doctor

Inactive ingredients: Benzalkonium Chloride, Boric Acid, Edetate Disodium, Purified Water, Sodium Chloride, Sodium Citrate

Distributed By:

Chain Drug Consortium, LLC.

3301 NW Boca Raton Blvd. Suite 101

Boca Raton, FL 33431

Enter section text here

PREMIER VALUE EYE AC

tetrahydrozoline hydrochloride and zinc sulfate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11716-0103
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
ZINC SULFATE (UNII: 89DS0H96TB) (ZINC - UNII:J41CSQ7QDS)	ZINC SULFATE	2.5 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 CITRATE (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11716-0103-2	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	11/02/2010	

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

Registrant - UNITED EXCHANGE CORP. (840130579)

Establishment

Name	Address	ID/FEI	Business Operations
HANLIM PHARM. CO., LTD.		687986034	manufacture

Revised: 11/2010 HANLIM PHARM. CO., LTD.