LEADER ORIGINAL FORMULA EYE DROPS - tetrahydrozoline hydrochloride solution/ drops
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

Tetrahydrozoline HCL 0.05%.....Redness reliever

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

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 25C (59 to 77F)

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

Enter section text here

LEADER ORIGINAL FORMULA EYE DROPS

tetrahydrozoline hydrochloride solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11716-4708
Route of Administration	OPHTHALMIC	**DEA Schedule**	CIV

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**
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11716-4708-8	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	03/22/2010	

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: 3/2010 HANLIM PHARM. CO., LTD.