

LEADER RELIEF EYE - tetrahydrozoline hcl, zinc sulfate solution/ drops
CARDINAL HEALTH

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

For external use only.

Do not use: If this solution changes color or becomes cloudy or if you are sensitive to any ingredient in this product.

When using this product

- remove contact lenses before using
- 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 eye gets worse 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 room temperature.
- 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 Cardinal Health

Dublin, OH 43017

CIN 1963735

www.myleader.com

1-800-200-6313



Enter section text here

LEADER RELIEF EYE

tetrahydrozoline hcl, zinc sulfate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-138
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0 YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL
ZINC SULFATE (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	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: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-138-05	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	01/04/2012	

Labeler - CARDINAL HEALTH (097537435)

Revised: 1/2012

CARDINAL HEALTH