

**FREDS ASTRINGENT REDNESS RELIEVER EYE - tetrahydrozoline hydrochloride solution**  
**Freds Inc**

*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.*

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**Drug Facts**

Active ingredients	Purpose
Tetrahydrozoline HCl 0.05%.....	Redness Reliever
Zinc Sulfate 0.25%.....	Astringent

Uses

- For temporary relief of discomfort and redness of the eye due to minor eye irritations

Warnings for external use only

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
- do not touch tips 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 they eye lasts
- condition worsens or lasts more than 72 hours

If pregnant or breast feeding, ask a health professional before use.

Keep out of 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
- Children under 6 years of age: Ask a doctor

Other information

- some users may experience a brief tingling sensation
- store between 15°-25°C (59°-77°F)

Inactive ingredients benzalkonium chloride, boric acid, disodium edetate hydrate, purified water, sodium chloride, sodium citrate

Distributed By:

Fred's Inc.

4300 New Getwell Rd.

Memphis, TN 38118

Made in Korea



<b>FREDS ASTRINGENT RDENESS RELIEVER EYE</b> tetrahydrozoline hydrochloride solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55315-124
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TETRAHYDROZOLINE HYDROCHLORIDE</b> (UNII: 0 YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.05 mg in 1 mg
<b>ZINC SULFATE</b> (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	ZINC SULFATE	0.25 mg in 1 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-124-15	1 in 1 CARTON		
1		15 mg in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	06/30/2013	

**Labeler** - Freds Inc (005866116)