

**REDNESS RELIEVER- tetrahydrozoline hcl liquid**  
**American Sales Company**

*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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**Careone Eye Drops Original**

**Active Ingredient**

Tetrahydrozoline HCl 0.5%

**Purpose**

Redness reliever

**Use**

- relieves redness of the eye due to minor eye irritations

**Warnings**

**Ask a doctor before use if you have**

narrow angle glaucoma

**When using this product**

- pupils may become enlarged temporarily
- to avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- if solution changes color or becomes cloudy, do not use
- overuse may produce increased redness of the eye
- remove contact lenses before using

**Stop use and ask a doctor if**

you experience

- eye pain
- changes in vision
- continued redness or irritation of the eye, or if the condition worsens or persists for 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.

**Other information**

- Store at 15° to 30°C (59°F to 86°F)

**Inactive ingredients**

benzalkonium chloride, boric acid, diluted hydrochloric acid, edetate disodium, purified water, sodium borate, sodium chloride

**package label**

Care One Redness Reliever



## REDNESS RELIEVER

tetrahydrozoline hcl liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-531
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TETRAHYDROZOLINE HYDROCHLORIDE</b> (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>SODIUM BORATE</b> (UNII: 91MBZ8H3QO)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-531-05	1 in 1 BOX	09/06/2011	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	09/06/2011	

**Labeler** - American Sales Company (809183973)

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American Sales Company