## 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 HCI 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

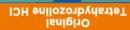
• Store at 15° to 30°C (59°F to 86°F)

## **Inactive ingredients**

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

## package label

Care One Redness Reliever



# EVE DROPS

### CYBEONG.

### **Drug Facts**

Active ingredient Purpose Tetrahydrozoline HCI 0.05% .. . Redness reliever

for the relief of 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 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 reach of children. If swallowed, get medical help or contact a Poison Control >

### Drug Facts (continued)

### Directions

put 1 to 2 drops in the affected eye(s) as needed - children under 6 years of age: ask a doctor

### Other information

- Do not use if the tamper-resistant bottle cap is broken or opened.
- store at 15° to 25°C (59° to 77°F)

### Inactive ingredients

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

## CARE**ONC**®

Compare to the Active Ingredients in Visine® Original\*

### **STERILE** EYE DROPS

Original Tetrahydrozoline HCI

REDNESS RELIEVER

### CAREONE'

## STERILE EYE DROPS

- . Do not use if the tamper-resistant bottle cap is broken or opened.
- · Retain This Carton For Future Reference
- Inis product is not immuractured or distributed by Consumer Health Care Group. Prize. Inc. . owner of the registered tracemark of visine® Original.

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CEDRG0051C01



1/2 FL 0Z

### **REDNESS RELIEVER**

tetrahydrozoline hcl liquid

### **Product Information**

**Product Type HUMAN OTC DRUG Item Code (Source)** NDC:41520-531

**Route of Administration OPHTHALMIC** 

### **Active Ingredient/Active Moiety**

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

Inactive Ingredients					
Ingredient Name	Strength				
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)					
BORIC ACID (UNII: R57ZHV85D4)					
HYDROCHLORIC ACID (UNII: QTT17582CB)					
EDETATE DISODIUM (UNII: 7FLD91C86K)					
WATER (UNII: 059QF0KO0R)					
SODIUM BORATE (UNII: 91MBZ8H3QO)					
SODIUM CHLORIDE (UNII: 451W47IQ8X)					

F	Packaging					
#	tem 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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