IRRITATION RELIEF EYE- tetrahydrozoline hydrochloride and zinc sulfate solution/ drops
WinCo Foods, LLC

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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Active ingredients
Tetrahydrozoline HCl 0.05%
Zinc sulfate 0.25%

Purpose
Tetrahydrozoline HCl...Redness Reliever
Zinc sulfate...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
• 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 lens 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 four times daily.

Other information
Store at 15°-30°C (59°-86°F)

Inactive ingredients
benzalkonium chloride, boric acid, edetate disodium, purified water, sodium chloride, and sodium citrate
**Drug Facts**

**Active ingredients**
- 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
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  - 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.

**Drug Facts (continued)**

**Purpose**
- Redness reliever
- Astringent

**Directions**
- Instill 1 or 2 drops in the affected eye(s) up to four times daily.

**Other information**
- Store at 15°C–30°C (59°C–86°F)
- Inactive ingredients:
  - Benzenethonium chloride, boric acid, edetate disodium, purified water, sodium chloride, and sodium citrate

**Irritation Relief Eye Drops**

STERILE REDNESS RELIEVER/ASTRINGENT
Relieves Irritation & Red Eyes
Seasonal Relief

0.5 FL OZ (15 mL)
# Irritation Relief Eye Drops

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:67091-283</th>
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<td>HUMAN OTC DRUG</td>
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<tr>
<td>OPHTHALMIC</td>
<td>DEA Schedule</td>
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## Active Ingredient/Active Moiety

<table>
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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D)</td>
<td>TETRAHYDROZOLINE</td>
<td>50 mg in 100 mL</td>
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<td>(TETRAHYDROZOLINE - UNII:S9U025Y077)</td>
<td>HYDROCHLORIDE</td>
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<tr>
<td>ZINC SULFATE (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)</td>
<td>ZINC CATION</td>
<td>250 mg in 100 mL</td>
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## Inactive Ingredients

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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)</td>
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<td>BORIC ACID (UNII: R57ZHV85D4)</td>
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<td>EDETA DISODIUM (UNII: 7FLD91C86K)</td>
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<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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<td>SODIUM CHLORIDE (UNII: 451W47Q8X)</td>
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<td>SODIUM CITRATE (UNII: 1Q73Q2JULR)</td>
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## Packaging

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<th>Package Description</th>
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<td>NDC:67091-283-15</td>
<td>1 in 1 BOX</td>
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<td>1</td>
<td>NDC:67091-283</td>
<td>15 mL in 1 BOTTLE, DROPPER</td>
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### Marketing Information

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<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>OTC monograph final</td>
<td>part349</td>
<td>01/09/2015</td>
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### Labeler
- WinCo Foods, LLC (056098817)

### Registrant
- KC Pharmaceuticals, Inc. (174450460)

### Establishment

<table>
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<tr>
<th>Name</th>
<th>Address</th>
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<th>Business Operations</th>
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<td>KC Pharmaceuticals, Inc.</td>
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<td>174450460</td>
<td>manufacture(67091-283), label(67091-283), pack(67091-283)</td>
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Revised: 2/2015

WinCo Foods, LLC