Drug Facts

Active ingredient
Ketotifen (0.025%)
(equivalent to ketotifen fumarate 0.035%)

Purpose
Antihistamine

Uses
Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.

Warnings

Do not use
- if solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product
- to treat contact lens related irritation

When using this product
- do not touch tip of container to any surface to avoid contamination
- remove contact lenses before use
- wait at least 10 minutes before reinserting contact lenses after use
- replace cap after each use

Stop use and ask a doctor if you experience any of the following:
- eye pain
- changes in vision
- redness of the eye
- itching worsens or lasts more than 72 hours

Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Adults and children 3 years of age and older:
  Put 1 drop in the affected eye(s) twice daily, every 8 to 12 hours, no more than twice per day.
- Children under 3 years of age:
  Consult a doctor.

Other information
- only for use in the eye
store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

**Inactive ingredients**
Benzalkonium Chloride 0.01%, Glycerin, Purified Water. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

**Questions or comments?**
1-866-696-0957

Principal Display Panel Text for Container Label:
NDC 50804-392-01
GOODSENSE® Logo
Itchy Eye Drops
Ketotifen Fumarate
Ophthalmic Solution
Antihistamine Eye Drops
0.17 FL OZ (5 mL) Sterile

Principal Display Panel Text for Carton Label:
NDC 50804-392-01
GOODSENSE® Logo
For Ages 3 Years & Older
Original Prescription Strength
Itchy Eye Drops
Ketotifen Fumarate
Ophthalmic Solution
Antihistamine Eye Drops
Allergy Itchy Eye Relief
Up To 12 Hours Itch Relief
• Works in Minutes
- 30 Day Supply
Compare to active ingredient of 100%
Zyrtec® SATISFACTION GUARANTEED
0.17 FL OZ (5 mL) Sterile
### Route of Administration

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketotifen Fumarate (UNII: HBD503WORO) (Ketotifen - UNII:X49220T18G)</td>
<td>Ketotifen</td>
<td>0.35 mg in 1 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium Chloride (UNII: F5UM2KM3W7)</td>
<td></td>
</tr>
<tr>
<td>Glycerin (UNII: PDC6A3C0OX)</td>
<td></td>
</tr>
<tr>
<td>Water (UNII: 059QF0KO0R)</td>
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<tr>
<td>Hydrochloric Acid (UNII: QTT17582CB)</td>
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<tr>
<td>Sodium Hydroxide (UNII: 55X04QC32I)</td>
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### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:50804-392-01</td>
<td>1 in 1 CARTON</td>
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<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>5 mL in 1 BOTTLE, DROPPER</td>
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### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>ANDA</td>
<td>ANDA077958</td>
<td>06/20/2014</td>
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### Labeler
- Good Sense (076059836)

### Registrant
- Akorn, Inc. (062649876)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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</thead>
<tbody>
<tr>
<td>Akorn, Inc</td>
<td>603980319</td>
<td>603980319</td>
<td>MANUFACTURE(50804-392), ANALYSIS(50804-392), STERILIZE(50804-392), PACK(50804-392), LABEL(50804-392)</td>
</tr>
</tbody>
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Revised: 6/2014