Drug Facts

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

Purpose
Antihistamine

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

Warnings
For external use only

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, Water for Injection. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

**Questions or comments?**
1-800-932-5676
Serious side effects associated with use of this product may be reported to this number

Principal Display Panel Text for Container Label:
CVS Health™ Logo
Eye Itch Relief
KETOTIFEN FUMARATE
OPHTHALMIC SOLUTION
0.035%
Antihistamine eye drops
STERILE
5 mL (0.17 FL OZ)

Principal Display Panel Text for Carton Label:
CVS Health™ Logo Compare to the active ingredient in Zaditor®*
NDC 59779-705-01
Eye Itch Relief
KETOTIFEN FUMARATE
OPHTHALMIC SOLUTION 0.035%
Antihistamine eye drops
• Works in minutes
• Original prescription strength
• For ages 3 and older
• 30 day supply
GET UP TO
12
HOURS
OF RELIEF
Actual Product
Size on Side Panel
STERILE
5 mL (0.17 FL OZ)
# EYE ITCH RELIEF
ketotifen fumarate solution/drops

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:59779-705</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th></th>
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<tbody>
<tr>
<td>OPHTHALMIC</td>
<td></td>
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## Active Ingredient/Active Moiety

<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>
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</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>benzalkonium chloride (UNII: F5UM2KM3W7)</td>
<td></td>
</tr>
<tr>
<td>glycerin (UNII: PDC6A3C0OX)</td>
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</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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</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:59779-705-01</td>
<td>1 in 1 CARTON</td>
<td>02/07/2014</td>
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<tr>
<td>1</td>
<td></td>
<td>5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product</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>02/07/2014</td>
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</table>

## Labeler
- CVS Pharmacy (062312574)

## 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>
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<td>603980319</td>
<td>MANUFACTURE(59779-705), ANALYSIS(59779-705), STERILIZE(59779-705), PACK(59779-705), LABEL(59779-705)</td>
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<tr>
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<td>-------------</td>
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<td>MANUFACTURE(59779-705)</td>
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<tbody>
<tr>
<td>Hi-Tech Pharmacal Co. Inc.</td>
<td></td>
<td>101196749</td>
<td>LABEL(59779-705), PACK(59779-705)</td>
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Revised: 11/2018