ALLERGY EYE DROPS- ketotifen fumarate solution/ drops
Advanced Vision Research (Subsidiary of Akorn, Inc.)

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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

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 for more than 72 hours

Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions
- Adults and children 3 years of age and older:
  Put 1 drop in the affected eye(s) twice daily, every 8-12 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°-25°C (68°-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?**
**1-800-579-8327**

Principal Display Panel Text for Container Label:
CVS pharmacy®
NDC 58790-301-02
ALLERGY EYE DROPS KETOTIFEN FUMARATE OPHTHALMIC SOLUTION ANTIHISTAMINE EYE DROPS 10 mL (0.34 FL OZ) STERILE

Principal Display Panel Text for Carton Label:
CVS pharmacy®
NDC 58790-301-02
Compare to the active ingredient in Alaway®*
NEW!
Contains the drug Ketotifen Fumarate
ALLERGY
EYE DROPS
KETOTIFEN FUMARATE
OPHTHALMIC SOLUTION
ANTIHISTAMINE
EYE DROPS
Works in minutes
- Original prescription strength
- For ages 3 years & older
- Relief for itchy eyes
- 60-day supply

up to
12
HOURS
10 mL ITCH RELIEF
(0.34 FL OZ)
STERILE
ALLERGY EYE DROPS
ketotifen fumarate solution/drops

Product Information

Product Type: HUMAN OTC DRUG
Route of Administration: OPHTHALMIC

Item Code (Source): NDC:58790-301-00

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>ketotifen fumarate (UNII: HBD503WORO)</td>
<td></td>
<td>0.35 mg in 1 mL</td>
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**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>benzalkonium chloride</td>
<td>(UNII: F5UM2KM3W7)</td>
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<tr>
<td>glycerin</td>
<td>(UNII: PDC6A3C0OX)</td>
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<tr>
<td>water</td>
<td>(UNII: 059QF0KO0R)</td>
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<tr>
<td>hydrochloric acid</td>
<td>(UNII: QTT17582CB)</td>
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<tr>
<td>sodium hydroxide</td>
<td>(UNII: 55X04QC32I)</td>
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**Packaging**

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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
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<th>Marketing End Date</th>
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<tr>
<td>1</td>
<td>NDC:58790-301-02</td>
<td>1 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>10 mL in 1 BOTTLE, DROPPER</td>
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**Marketing Information**

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<thead>
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<th>Marketing Category</th>
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<th>Marketing End Date</th>
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<tr>
<td>ANDA</td>
<td>ANDA077958</td>
<td>11/14/2013</td>
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**Labeler** - Advanced Vision Research (Subsidiary of Akorn, Inc.) (969124536)

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

**Establishment**

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<thead>
<tr>
<th>Name</th>
<th>Address</th>
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<th>Business Operations</th>
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<tbody>
<tr>
<td>Akorn, Inc</td>
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<td>603980319</td>
<td>MANUFACTURE(58790-301) , ANALYSIS(58790-301) , STERILIZE(58790-301) , PACK(58790-301) , LABEL(58790-301)</td>
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Revised: 11/2013