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.

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° to 25°C (68° TO 77°F) [see USP Controlled Room Temperature].
Inactive ingredients
Benzalkonium Chloride 0.01%; Glycerin and Purified Water. May contain Hydrochloric Add and/or Sodium Hydroxide (to adjust pH).

Questions?
call toll-free 1-800-932-5676, weekdays, 7:00 AM - 5:30 PM CST

Principal Display Panel Text for Container Label:
NDC 17478-717-10
Ketotifen Fumarate
Ophthalmic Solution
ANTIHISTAMINE EYE DROPS
5 mL (0.17 FL OZ) Sterile

Principal Display Panel Text for Carton Label:
Now OTC! NDC 17478-060-12
Akorn Logo
Ketotifen
Fumarate
Ophthalmic Solution
ANTIHISTAMINE EYE DROPS
UP TO 12 HOURS EYE ITCH RELIEF
Works in Minutes
Original Prescription Strength
FOR AGES 3 YEARS AND OLDER
30 DAY SUPPLY
5 mL (0.17 FL OZ) Sterile
## Product Information

### Product Type
- **HUMAN OTC DRUG**

### Route of Administration
- **OPHTHALMIC**

### Product Information

<table>
<thead>
<tr>
<th>Item Code (Source)</th>
<th>NDC:17478-717</th>
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</table>

### 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: HBD503WOR0) (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>
</tr>
</thead>
<tbody>
<tr>
<td>benzalkonium chloride (UNII: F5UM2KMM3W7)</td>
<td></td>
</tr>
<tr>
<td>glycerin (UNII: PDC6A3C0OX)</td>
<td></td>
</tr>
<tr>
<td>water (UNII: 059Q0K00R)</td>
<td></td>
</tr>
<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:17478-717-10</td>
<td>1 in 1 CARTON</td>
<td>10/01/2007</td>
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</tr>
<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

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<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>10/01/2007</td>
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**Labeler - 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 AG</td>
<td>482198285</td>
<td>MANUFACTURE(17478-717) , ANALYSIS(17478-717) , PACK(17478-717) , LABEL(17478-717)</td>
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</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Akorn, Inc.</td>
<td>603980319</td>
<td>MANUFACTURE(17478-717) , REPACK(17478-717) , ANALYSIS(17478-717) , LABEL(17478-717) , PACK(17478-717) , RELABEL(17478-717) , STERILIZE(17478-717)</td>
<td></td>
</tr>
</tbody>
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Revised: 11/2017