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 Water for Injection. May contain Hydrochloric Acid 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 0179-8601-05
KAISER PERMANENTE® Logo
Ketotifen Fumarate
Ophthalmic Solution
Antihistamine Eye Drop
5 mL (0.17 FL OZ) Sterile

Principal Display Panel Text for Carton Label:
NDC 0179-8601-05
KAISER PERMANENTE® Logo
Ketotifen
Fumarate
Ophthalmic Solution
Antihistamine
Eye drop
Up to 12 hours of eye itch relief
0.025% Sterile solution
*Compare to Zaditor®
5 mL (0.17 FL OZ)
**Ketotifen Fumarate**
ketotifen fumarate solution/ drops

### Product Information

<table>
<thead>
<tr>
<th><strong>Product Type</strong></th>
<th>HUMAN OTC DRUG</th>
<th><strong>Item Code (Source)</strong></th>
<th>NDC:0179-8601</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Route of Administration</strong></td>
<td>OPHTHALMIC</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: HBD503WOR0) (KETOTIFEN - UNII:X49220T18G)</td>
<td>KETOTIFEN</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>
</tr>
</thead>
<tbody>
<tr>
<td>BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)</td>
<td></td>
</tr>
<tr>
<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
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<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:0179-8601-05</td>
<td>1 in 1 CARTON</td>
<td>11/08/2011</td>
<td>11/01/2020</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

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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>11/08/2011</td>
<td>11/01/2020</td>
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### Labeler - KAISER FOUNDATION HOSPITALS (053052619)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>Akorn AG</td>
<td>482198285</td>
<td>manufacture(0179-8601) , analysis(0179-8601) , pack(0179-8601) , label(0179-8601)</td>
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<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Akorn, Inc.</td>
<td>603980319</td>
<td>manufacture(0179-8601) , repack(0179-8601) , analysis(0179-8601) , label(0179-8601) , pack(0179-8601) , relabel(0179-8601) , sterilize(0179-8601)</td>
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Revised: 11/2018