**KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops**
**KAISER FOUNDATION HOSPITALS**

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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.

**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

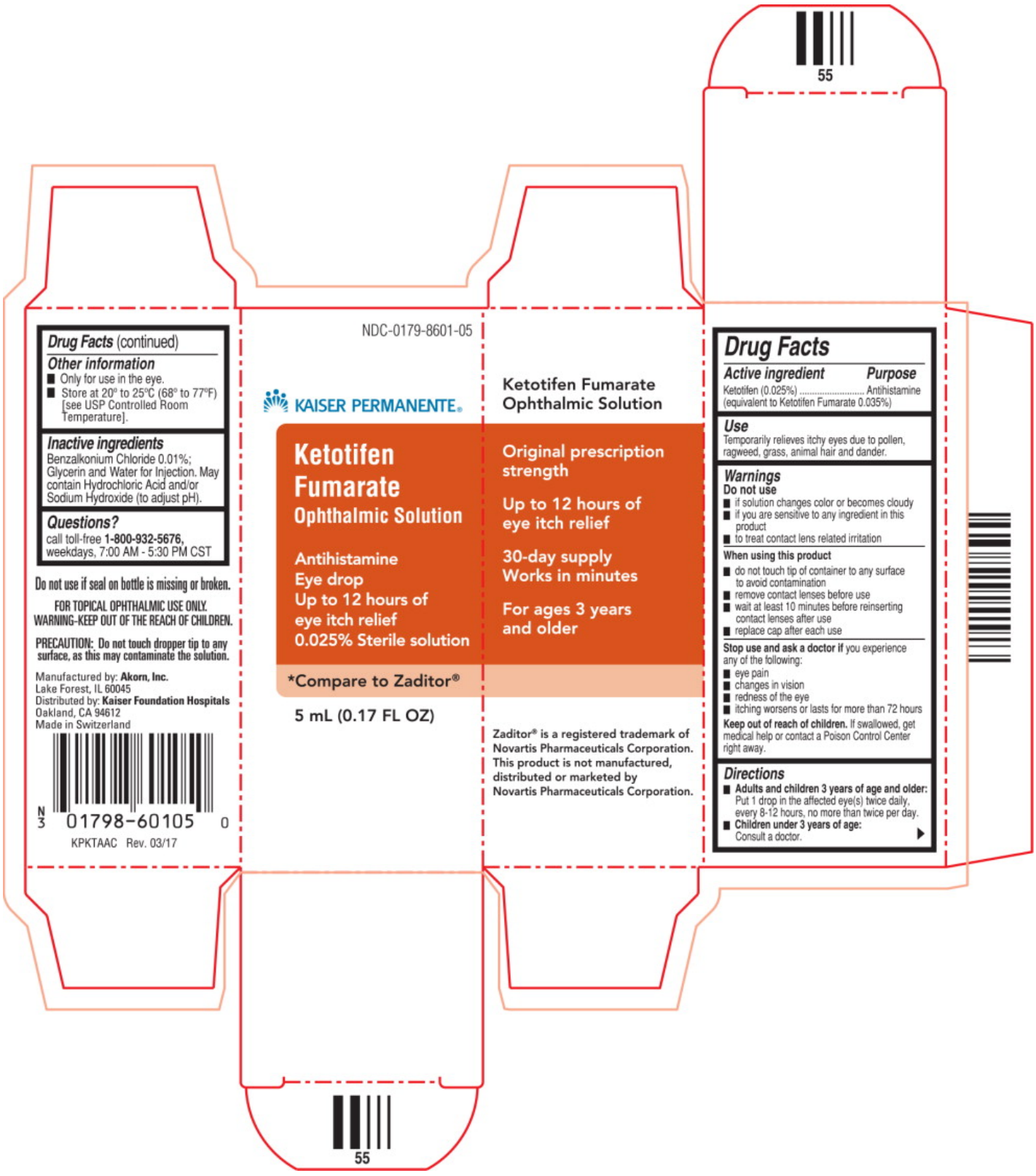
Up to 12 hours of

eye itch relief

0.025% Sterile solution

*Compare to Zaditor ®

5 mL (0.17 FL OZ)




# KETOTIFEN FUMARATE

ketotifen fumarate solution/ drops

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0179-8601 |
| **Route of Administration** | OPHTHALMIC | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **KETOTIFEN FUMARATE** (UNII: HBD503WORO) (KETOTIFEN - UNII:X49220T18G) | KETOTIFEN | 0.35 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **HYDROCHLORIC ACID** (UNII: QTT17582CB) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0179-8601-05 | 1 in 1 CARTON | 11/08/2011 | 11/01/2020 |
| **1** | | 5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA077958 | 11/08/2011 | 11/01/2020 |

## Labeler - KAISER FOUNDATION HOSPITALS (053052619)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Akorn AG | | 482198285 | manufacture(0179-8601) , analysis(0179-8601) , pack(0179-8601) , label(0179-8601) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Akorn, Inc. | | 603980319 | manufacture(0179-8601) , repack(0179-8601) , analysis(0179-8601) , label(0179-8601) , pack(0179-8601) , relabel(0179-8601) , sterilize(0179-8601) |

Revised: 11/2018 KAISER FOUNDATION HOSPITALS