

KETOTIFEN FUMARATE- ketotifen fumarate solution
Strategic Sourcing Services LLC

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 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 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°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].

Inactive ingredients

benzalkonium chloride 0.01%, glycerol, hydrochloric acid and/or sodium hydroxide, and water for injection

Questions or comments?

call us at **1-800-706-5575** (Monday to Friday 8:30 am – 5:00 pm Eastern Standard Time)

Principal Display Panel - Bottle Label

McKesson - HealthMart

NDC 62011-0379-1

Ketotifen Fumarate Ophthalmic Solution 0.025% 5 ml bottle



Principal Display Panel - Bottle Carton

McKesson - HealthMart

NDC 62011-0379-1

Ketotifen Fumarate Ophthalmic Solution 0.025% 5 ml bottle

9211707



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NDC 62011-0379-1

**HealthMart.**Compare to Zaditor®
active ingredient*

Eye Itch Relief

Ketotifen Fumarate**Sterile
Antihistamine Eye Drops****Up to 12 Hours
OPHTHALMIC SOLUTION**Works in Minutes
Original Prescription Strength
For ages 3 years and older
30 day supply

5 mL (0.17 FL OZ)

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Drug Facts (continued)**Stop use and ask a doctor if you experience any of the following:**

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Drug Facts (continued)

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Questions or comments?Write to: Apotex Corp.
Consumer Affairs
2400 N. Commerce Pkwy,
Suite 400, Weston FL 33326
or call us at **1-800-706-5575**
(Monday to Friday 8:30 am – 5:00 pm
Eastern Standard Time)

*This product is not manufactured or distributed by Alcon a Novartis Company, distributor of Zaditor®

Important: Read all product information before using. Keep package as it contains important information.

TAMPER EVIDENT: DO NOT USE IF SEAL ON CARTON IS BROKEN OR MISSING.**McKesson**McKesson Corporation
6555 State Highway 161
Irving, TX 75039
Money Back Guarantee
www.healthmart.com
Made in Canada

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KETOTIFEN FUMARATE

ketotifen fumarate solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62011-0379 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| Ketotifen Fumarate (UNII: HBD503WORO) (Ketotifen - UNII:X49220T18G) | Ketotifen | 0.25 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:62011-0379-1 | 1 in 1 CARTON | 06/18/2019 | |
| 1 | | 5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA077354 | 06/18/2019 | |

Labeler - Statagic Sourcing Services LLC (116956644)