

EYE ITCH RELIEF- ketotifen fumarate solution/ drops

Walgreens

Drug Facts

Active ingredient

Ketotifen (0.025%)

Purpose

Antihistamine

(equivalent to ketotifen fumarate 0.035%)

Uses

For the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.

Warnings

Do not use

- if you are sensitive to any ingredient in this product
- if solution changes color or becomes cloudy
- to treat contact lens related irritation

When using this product

- remove contact lenses before use
- wait at least 10 minutes before re-inserting contact lenses after use
- do not touch tip of container to any surface to avoid contamination
- 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 eyes
- itching that 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 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

- store at 4-25°C (39-77°F)

Inactive ingredients

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

Questions or comments?

Toll Free Product Information

Call: 1-800-553-5340

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

100% SATISFACTION GUARANTEED

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MADE IN U.S.A.

ITEM 306486

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FU60107

Principal Display Panel

Well at

Walgreens

WALGREENS PHARMACIST RECOMMENDED[‡]

STERILE

ORIGINAL

PRESCRIPTION STRENGTH

Eye Itch

Relief

Ketotifen Fumarate

Ophthalmic Solution

Antihistamine Eye Drops

- Works in minutes
- For ages 3 years & older
- 30-day supply

0.17 FL OZ (5 mL)

12 UP TO 12 HOURS

Compare to Zaditor[®] active ingredient^{††}



EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-0610 |
| 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 |
|--|----------|
| Benzalkonium Chloride (UNII: F5UM2KM3W7) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Hydrochloric Acid (UNII: QTT17582CB) | |
| Sodium Hydroxide (UNII: 55X04QC3I) | |
| Water (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------|----------------------|--------------------|
| 1 | NDC:0363-0610-10 | 2 in 1 CARTON | | |
| 1 | | 5 mL in 1 BOTTLE, DROPPER | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA077958 | 05/01/2012 | |

Labeler - Walgreens (008965063)**Registrant** - Advanced Vision Research (Subsidiary of Akorn, Inc.) (969124536)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|--|
| Akorn, Inc | | 603980319 | MANUFACTURE(0363-0610) , ANALYSIS(0363-0610) , STERILIZE(0363-0610) , PACK(0363-0610) , LABEL(0363-0610) |

Revised: 9/2014

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