

ALLERGY EYE DROPS- ketotifen fumarate solution/ drops
Advanced Vision Research (Subsidiary of Akorn, Inc.)

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. (1-800-222-1222)

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°-25°C (68°-77°F) [see USP Controlled Room Temperature]

Inactive ingredients

benzalkonium chloride 0.01%, glycerin, purified water. May contain hydrochloric acid and/or sodium hydroxide (to adjust pH).

Questions or comments?

1-800-579-8327

Principal Display Panel Text for Container Label:

CVS

pharmacy®

NDC 58790-301-02

ALLERGY

EYE DROPS

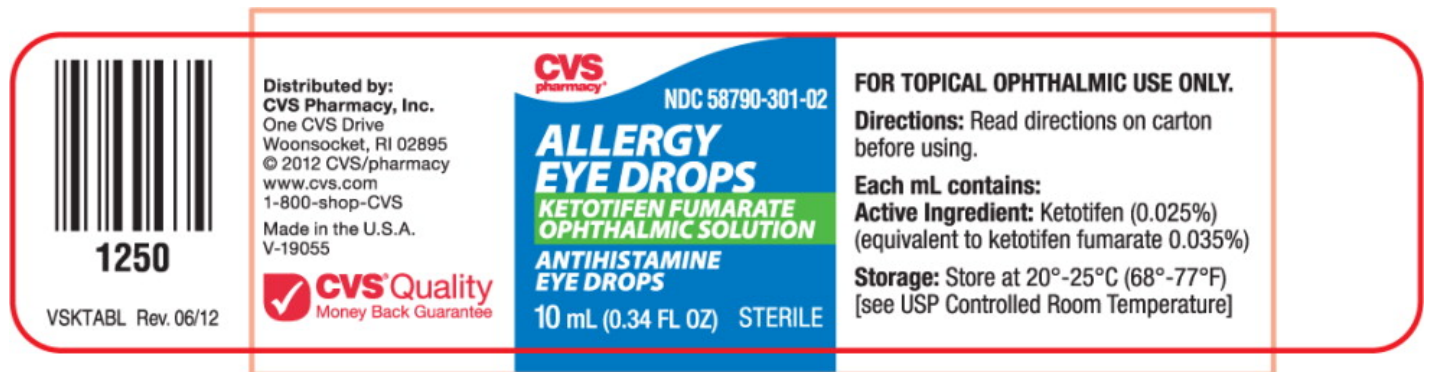
KETOTIFEN FUMARATE

OPHTHALMIC SOLUTION

ANTI-HISTAMINE

EYE DROPS

10 mL (0.34 FL OZ) STERILE



Principal Display Panel Text for Carton Label:

CVS

pharmacy®

NDC 58790-301-02

Compare to the active ingredient

in Alaway®*

NEW!

Contains the drug

Ketotifen Fumarate

ALLERGY

EYE DROPS

KETOTIFEN FUMARATE

OPHTHALMIC SOLUTION

ANTI-HISTAMINE

EYE DROPS

Works in minutes

- Original prescription strength
- For ages 3 years & older
- Relief for itchy eyes
- 60-day supply

up to

12

HOURS

10 mL ITCH RELIEF

(0.34 FL OZ)

STERILE



ALLERGY EYE DROPS

ketotifen fumarate solution/ drops

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58790-301 |
| 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: 059QF0K00R) | |
| hydrochloric acid (UNII: QTT17582CB) | |
| sodium hydroxide (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:58790-301-02 | 1 in 1 CARTON | | |
| 1 | | 10 mL in 1 BOTTLE, DROPPER | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA077958 | 11/14/2013 | |

Labeler - Advanced Vision Research (Subsidiary of Akorn, Inc.) (969124536)

Registrant - Akorn, Inc. (062649876)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|--|
| Akorn, Inc | | 603980319 | MANUFACTURE(58790-301) , ANALYSIS(58790-301) , STERILIZE(58790-301) , PACK(58790-301) , LABEL(58790-301) |

Revised: 11/2013

Advanced Vision Research (Subsidiary of Akorn, Inc.)