

**KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops**  
**CVS Pharmacy**

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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**

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

### Inactive ingredients

Benzalkonium Chloride 0.01%, Glycerin, Water for Injection. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

### Questions or comments?

1-800-932-5676

Serious side effects associated with use of this product may be reported to this number

Principal Display Panel Text for Container Label:

CVS Health™ Logo

NDC 59779-627-01

Eye Itch Relief

Antihistamine

eye drops

KETOTIFEN FUMARATE

OPHTHALMIC

SOLUTION 0.035% STERILE

0.17 FL OZ (5 mL)



Principal Display Panel Text for Carton Label:

CVS Health™ Logo Compare to the active

ingredient in Zaditor®\*

NDC 59779-627-01

Original Prescription Strength

Eye Itch

Relief

KETOTIFEN FUMARATE

OPHTHALMIC SOLUTION 0.035%

Antihistamine eye drops

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

GET UP TO

12

HOUR

RELIEF

Actual Product

Size on Side Panel

STERILE

5 mL (0.17 FL OZ)



## KETOTIFEN FUMARATE

ketotifen fumarate solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-627
<b>Route of Administration</b>	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
<b>benzalkonium chloride</b> (UNII: F5UM2KM3W7)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>hydrochloric acid</b> (UNII: QTT17582CB)	
<b>sodium hydroxide</b> (UNII: 55X04QC32I)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-627-01	1 in 1 CARTON	11/08/2013	
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	11/08/2013	

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - Akorn Operating Company LLC (117693100)

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(59779-627) , ANALYSIS(59779-627) , STERILIZE(59779-627) , PACK(59779-627) , LABEL(59779-627)

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn, AG		482198285	MANUFACTURE(59779-627)

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	LABEL(59779-627) , PACK(59779-627)