

**KETOTIFEN FUMARATE- ketotifen fumarate solution**  
**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 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?**

Write to:

Apotex Corp.

Consumer Affairs

2400 N. Commerce Pkwy,

Suite 400,

Weston FL 33326

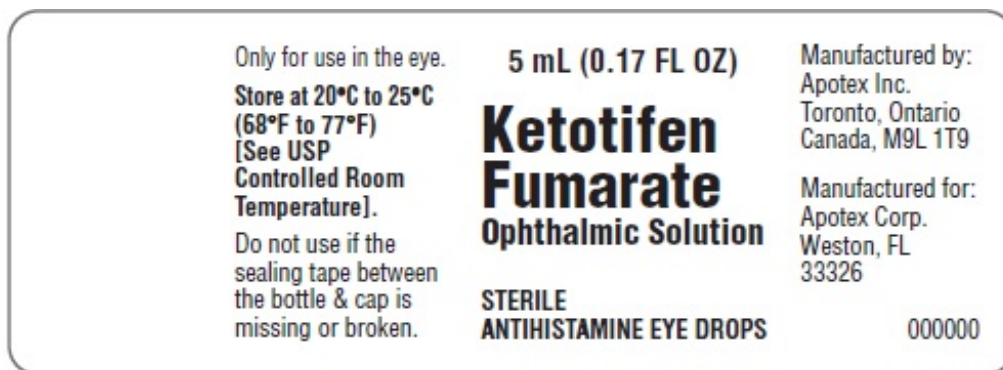
or call us at **1-800-706-5575** (Monday to Friday 8:30 am – 5:00 pm Eastern Standard Time)

**Principal Display Panel - Bottle Label**

CVS Pharmacy

NDC 69842-600-01

Ketotifen Fumarate Ophthalmic Solution 0.025% 5 ml bottle



**Principal Display Panel - Bottle Carton**

CVS Pharmacy

NDC 69842-600-01

Ketotifen Fumarate Ophthalmic Solution 0.025% 5 ml bottle



## KETOTIFEN FUMARATE

ketotifen fumarate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-600
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Ketotifen Fumarate</b> (UNII: HBD503WORO) (Ketotifen - UNII:X49220T18G)	Ketotifen	0.25 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Hydrochloric Acid</b> (UNII: QTT17582CB)	
<b>Benzalkonium Chloride</b> (UNII: F5UM2KM3W7)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-600-01	1 in 1 CARTON	06/01/2018	
1		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:69842-600-02	2 in 1 CARTON	06/01/2018	
2		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	06/01/2018	

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - Apotex Inc (209429182)

### Establishment

Name	Address	ID/FEI	Business Operations
Apotex Inc		255092496	analysis(69842-600) , manufacture(69842-600)

### Establishment

Name	Address	ID/FEI	Business Operations
Sifavitor SPA		437723684	api manufacture(69842-600)

Revised: 6/2018

CVS Pharmacy