

EYE ITCH RELIEF- ketotifen fumarate solution
Walgreen Company

Drug Facts

Active ingredient

Ketotifen 0.025%
(equivalent to ketotifen fumarate 0.035%)

Purpose

Antihistamine

Uses

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

Warnings

For external use only

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
 - if using other ophthalmic products while using this product, wait at least 5 minutes between each product
- **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, water for injection

Questions or comments?

{phone icon} **Call: 1-800-459-6906**

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Package/Label Principal Display Panel

VALUE SIZE

NDC 0363-0038-10

Walgreens

Compare to Systane ZADITOR active ingredient ††

**Eye Itch
Relief**

**ketotifen fumarate
ophthalmic solution 0.035%
ANTIHISTAMINE EYE DROPS**

Up to 12 Hours

- Original prescription strength
- Works in minutes
- 60 day supply
- For ages 3
- years and older
- STERILE 0.34 FL OZ (10 mL)



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NDC 0363-0038-10

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Compare to the active
ingredient in Alaway[®]††

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- 9765901

3652

**EYE ITCH RELIEF**

ketotifen fumarate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0038	
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)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0038-05	1 in 1 CARTON	09/03/2013	
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0038-10	1 in 1 CARTON	09/03/2013	
2		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	NDA021996		09/03/2013	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	manufacture(0363-0038)