

KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops

Walgreens

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

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 eye s
- 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 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 306487

9323200

FU60109

Principal Display Panel

VALUE SIZE

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
- 60-day supply

UP TO 12 HOURS

0.34 FL OZ (10 mL)

Compare to Zaditor® active ingredient#



KETOTIFEN FUMARATE

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9060
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: 55X04QC32I)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9060-00	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	01/25/2013	

Labeler - Walgreens (008965063)

Registrant - Akorn, Inc. (062649876)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc		603980319	MANUFACTURE(0363-9060) , ANALYSIS(0363-9060) , STERILIZE(0363-9060) , PACK(0363-9060) , LABEL(0363-9060)

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