

ZADITOR - ketotifen fumarate solution
Alcon Laboratories, Inc.

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Ketotifen (0.025%) (equivalent to ketotifen fumarate 0.035%)	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 8-12 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 between 4°-25°C (39°-77°F).

Inactive ingredients

benzalkonium chloride 0.01%, glycerol, purified water, sodium hydroxide and/or hydrochloric acid

Questions?

In the US, call toll-free **1-800-757-9195**

alcon.medinfo@alcon.com

www.systeme.com

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

New Look SAME FORMULA

**Systeme®
ZADITOR**

ketotifen fumarate ophthalmic solution 0.035%

ANTI-HISTAMINE EYE DROPS

up to 12 HOURS EYE ITCH RELIEF

- Works in minutes
- Original prescription strength
- For ages 3 years and older

5 mL (0.17 FL OZ)

STERILE

30 DAY SUPPLY

Alcon®

TAMPER EVIDENT: For your protection, this bottle has a seal imprinted with Alcon around the neck. Do not use if seal is damaged or missing at time of purchase.

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134 USA
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9013176-0416

ACTUAL SIZE

LOT: EXP.:



Systane[®]
ZADITOR[®]
ketotifen fumarate ophthalmic solution 0.035%

ANTI-HISTAMINE EYE DROPS
EYE ITCH RELIEF

- Works in minutes
- Original prescription strength
- For ages 3 years and older

up to 12 HOURS

Alcon

STERILE
30 DAY SUPPLY
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***Original Prescription Strength
Up to 12 Hour Itch Relief
Works in Minutes***

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Alcon Laboratories, Inc.
Fort Worth, TX 76134 USA
a Novartis Division
Country of Origin: Italy

9016645-0918

ACTUAL SIZE

LOT: EXP.:



ZADITOR

ketotifen fumarate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0065-4011
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ketotifen Fumarate (UNII: HBD503WORO) (Ketotifen - UNII:X49220T18G)	Ketotifen	.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7)	

Glycerin (UNII: PDC6A3C0OX)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-4011-05	1 in 1 CARTON	12/21/2012	
1		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:0065-4011-06	2 in 1 CARTON	12/21/2012	
2		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:0065-4011-11	3 in 1 CARTON	12/21/2012	
3		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	ANDA077200	12/21/2012	

Labeler - Alcon Laboratories, Inc. (008018525)

Registrant - Alcon Research Ltd (007672236)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Research LLC		007672236	manufacture(0065-4011)