

**ZADITOR - ketotifen fumarate solution**  
**Alcon Laboratories, Inc.**

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***Drug Facts***

<b><i>Active ingredient</i></b>	<b><i>Purpose</i></b>
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**

**Systeme®**

**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**

5mL (0.17 FL OZ)

***Original Prescription Strength***

***Up to 12 Hour Itch Relief***

***Works in Minutes***

**For Ages 3 Years and Older**

**30 DAY SUPPLY**

**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.

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)	

<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Hydrochloric Acid</b> (UNII: QTT17582CB)	
<b>Water</b> (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 LLC (007672236)

**Establishment**

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