

**EYE ITCH RELIEF- ketotifen fumarate solution/ drops**  
**Cardinal Health**

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***Drug Facts***

**Active Ingredient**

Ketotifen (0.025%) (equivalent to ketotifen fumarate 0.035%)

**Purpose**

Antihistamine

**Uses**

Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.

**Warnings**

**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 the tip of container to any surface to avoid contamination
- remove contact lenses before use
- wait at least 10 minutes before reinserting contact lens 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 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° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

## Inactive ingredients

Benzalkonium Chloride 0.01%, Glycerin, Water for Injection. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

## Questions or comments?

1-800-932-5676

## Principal Display Panel Text for Container Label:

LEADER™ Logo

NDC 70000-0124-1

Sterile

Eye Itch

Relief

Ketotifen Fumarate Ophthalmic Solution

Antihistamine Eye Drops

5 mL (0.17FL OZ)



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Sterile

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Ketotifen Fumarate Ophthalmic Solution

Antihistamine Eye Drops

Up to 12 Hours

of Itch Relief COMPARE TO

Works in Minutes ZADITOR®

Original Prescription ANTIHISTAMINE

Strength EYE DROPS

Active ingredient\*

For Ages 3 Years

& Older 100% Money

30-day Supply Back Guarantee

5 mL (0.17 FL OZ)

**LEADER<sup>TM</sup>**

**Eye Itch Relief**  
Ketotifen Fumarate Ophthalmic Solution  
Up to 12 Hours of Itch Relief

**LEADER<sup>TM</sup>** **LEADER<sup>TM</sup>**

**Eye Itch Relief**  
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**Up to 12 Hours of Itch Relief**  
Works in Minutes  
Original Prescription Strength  
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**COMPARE TO ZADITOR<sup>®</sup> ANTIHISTAMINE EYE DROPS active ingredient\***

**100% Money Back Guarantee**

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**Drug Facts (continued)**

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**FOR TOPICAL OPHTHALMIC USE ONLY**  
**WARNING: KEEP OUT OF THE REACH OF CHILDREN**  
**PRECAUTION:** Do not touch dropper tip to any surface, as this may contaminate the solution  
**DO NOT USE:** IF IMPRINTED SEAL ON BOTTLE IS MISSING OR BROKEN  
\*This product is not manufactured or distributed by Alcon Laboratories, distributor of Zaditor<sup>®</sup>.

**CardinalHealth<sup>TM</sup>**  
DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myleader.com 1-800-200-6313  
Essential to Care<sup>®</sup> since 1979

**100% Money Back Guarantee**  
Return to place of purchase.

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## EYE ITCH RELIEF

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### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70000-0124

**Route of Administration** OPTHALMIC

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Ketotifen Fumarate</b> (UNII: HBD503WORO) (Ketotifen - UNII:X49220T18G)	Ketotifen	0.35 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Benzalkonium Chloride</b> (UNII: F5UM2KM3W7)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Hydrochloric Acid</b> (UNII: QTT17582CB)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0124-1	1 in 1 CARTON	01/18/2017	
1		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	ANDA077958	01/18/2017	

**Labeler** - Cardinal Health (097537435)

**Registrant** - Akorn, Inc. (062649876)

### Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc		603980319	MANUFACTURE(70000-0124) , ANALYSIS(70000-0124) , STERILIZE(70000-0124) , PACK(70000-0124) , LABEL(70000-0124)

Revised: 1/2017

Cardinal Health