

**EYE ITCH- ketotifen fumarate solution/ drops**  
**Meijer Distribution Inc**

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**Drug Facts**

**Active ingredient**

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

**Purpose**

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 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. (1-800-222-1222)

**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?

**1-800-923-5676**

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

Principal Display Panel Text for Container Label:

NDC 41250-302-01

meijer logo®

eye itch relief

Ketotifen Fumarate

Ophthalmic Solution 0.035%

Antihistamine Eye Drops

5 mL (0.17 FL OZ)

Sterile



Principal Display Panel Text for Carton Label:

NDC 41250-302-01

Compare to Zaditor®

active ingredient\*

meijer Logo®

ORIGINAL

PRESCRIPTION

STRENGTH

eye itch

relief

Ketotifen Fumarate

Ophthalmic Solution 0.035%

Antihistamine Eye Drops

Up to 12 Hours of Relief

Works in Minutes

STERILE

30 Day Supply

5 mL (0.17 FL OZ)



## EYE ITCH

ketotifen fumarate solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41250-302
<b>Route of Administration</b>	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
<b>benzalkonium chloride</b> (UNII: F5UM2KM3W7)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>water</b> (UNII: 059QF0K00R)	
<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:41250-302-01	1 in 1 CARTON	01/23/2014	
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	01/23/2014	

**Labeler** - Meijer Distribution Inc (006959555)

**Registrant** - Akorn Operating Company LLC (117693100)

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(41250-302) , ANALYSIS(41250-302) , STERILIZE(41250-302) , PACK(41250-302) , LABEL(41250-302)

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(41250-302)

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	PACK(41250-302) , LABEL(41250-302)