

**EYE ITCH RELIEF- ketotifen fumarate solution/ drops**  
**Rite Aid Corporation**

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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 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. (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?**

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

**1-800-932-5676**

Principal Display Panel Text for Container Label:

Rite Aid Pharmacy Logo®

ORIGINAL

PRESCRIPTION STRENGTH

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:

TWIN PACK

Rite Aid Pharmacy Logo®

\*Compare to the active ingredient of Zaditor®

ORIGINAL PRESCRIPTION STRENGTH

eye itch

relief

ketotifen fumarate

ophthalmic solution 0.035%

antihistamine eye drops

UP TO 12 HOURS ITCH RELIEF

works in minutes

for ages 3 years and older

60-day supply

**2**

Sterile 1 - 5 mL

(0.17 FL OZ) BOTTLES



## EYE ITCH RELIEF

ketotifen fumarate solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-4202
<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
benzalkonium chloride (UNII: F5UM2KM3W7)	
glycerin (UNII: PDC6A3C00X)	
water (UNII: 059QF0KO0R)	

hydrochloric acid (UNII: QTT17582CB)

sodium hydroxide (UNII: 55X04QC32I)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-4202-0	2 in 1 CARTON	12/06/2013	
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	12/06/2013	

**Labeler** - Rite Aid Corporation (014578892)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(11822-4202) , ANALYSIS(11822-4202) , STERILIZE(11822-4202) , PACK(11822-4202) , LABEL(11822-4202)

### Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(11822-4202)

### Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	LABEL(11822-4202) , PACK(11822-4202)

Revised: 2/2022

Rite Aid Corporation