

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

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?

1-800-932-5676

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

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:

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

30-day supply

Sterile

5 mL

(0.17 FL OZ)



EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-4201
Route of Administration	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: PDC6A3C0OX)	
water (UNII: 059QF0KO0R)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-4201-0	1 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(11822-4201) , ANALYSIS(11822-4201) , STERILIZE(11822-4201) , PACK(11822-4201) , LABEL(11822-4201)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(11822-4201)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	LABEL(11822-4201) , PACK(11822-4201)