

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

Uses

for the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.

Warnings

For external use only

Do not use

- if you are sensitive to any ingredient in this product
- if solution changes color or becomes cloudy
- to treat contact lens related irritation

When using this product

- remove contact lenses before use
- wait at least 10 minutes before re-inserting contact lenses after use
- do not touch tip of container to any surface to avoid contamination
- 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 eyes
- itching that 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 and older:**
 - put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day
 - if using other ophthalmic products while using this product, wait at least 5 minutes between each product
- **children under 3 years of age:** consult a doctor

Other information

store at 4-25°C (39-77°F)

Inactive ingredients

benzalkonium chloride 0.01%, glycerin, hydrochloric acid and/or sodium hydroxide, water for injection

Questions or comments?

Call: 1-866-767-8975

Package/Label Principal Display Panel

1009

Eye Itch Relief

ketotifen fumarate
ophthalmic solution 0.035%
ANTIHISTAMINE EYE DROPS

NDC 11822-5533-1

Compare to Zaditor®
Active ingredient*

Eye Itch Relief

ketotifen fumarate
ophthalmic solution 0.035%
ANTIHISTAMINE EYE DROPS

up to 12 hours
works in minutes
Original prescription
strength
for ages 3 years and older



STERILE

0.34 FL. OZ. (10 mL)

DO NOT USE IF IMPRINTED
NECKBAND "PROTECTIVE SEAL"
WITH YELLOW  IS NOT INTACT.
*This product is not manufactured or distributed
by Novartis AG owner of the trademark Zaditor®.
DISTRIBUTED BY: RITE AID
30 HUNTER LANE
CAMP HILL, PA 17011
www.riteaid.com
PRODUCT OF ITALY
SATISFACTION GUARANTEE
If you're not satisfied,
we'll happily refund your money.



Drug Facts

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Drug Facts (continued)

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Lot and exp area

6001

NDC 11822-5533-1

Compare to **Zaditor®**
Active ingredient*

**Eye Itch
Relief**

ketotifen fumarate
ophthalmic solution 0.035%
ANTI-HISTAMINE EYE DROPS

up to 12 hours

works in minutes

**Original prescription
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for ages 3 years and older

STERILE

0.34 FL OZ (10 mL)

EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-5533
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
KETOTIFEN FUMARATE (UNII: HBD503WORO) (KETOTIFEN - UNII:X49220T18G)	KETOTIFEN	0.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-5533-1	1 in 1 CARTON	04/01/2022	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
NDA	NDA021996	04/01/2022	

Labeler - Rite Aid Corporation (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(11822-5533) , PACK(11822-5533) , LABEL(11822-5533)

Revised: 12/2021

Rite Aid Corporation