

KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops
Rugby Laboratories

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 doctor if you experience any of the following:

- eye pain
- changes in vision
- redness of the eyes
- itching that worsens or lasts more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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.

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?

Toll Free Product Information

Call: 1-800-645-2158

Distributed by:

RUGBY® LABORATORIES

17177 N Laurel Park Drive

Suite 233, Livonia, MI 48152

www.rugbylaboratories.com

Product of Italy

Package/Label Principal Display Panel

3489

ANTHISTAMINE EYE DROPS
ophthalmic solution, 0.035%
ketotifen fumarate
Eye Itch Relief
Rugby

NDC 0536-1252-40

Compare to the active ingredient in Zaditor*

Rugby

Eye Itch Relief
ketotifen fumarate
ophthalmic solution, 0.035%
ANTHISTAMINE EYE DROPS



- Works in Minutes
- Original Prescription Strength
- For Ages 3 Years and Older

STERILE **5 mL**
(0.17 FL OZ)

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.

Keep carton for full Drug Facts information.



Drug Facts

Active ingredient Ketotifen 0.025% **Purpose** Antihistamine (equivalent to ketotifen fumarate 0.035%)

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 (1-800-222-1222) 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. Children under 3 years of age: consult a doctor

Drug Facts (continued)

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?
Toll Free Product Information
Call 1-800-845-2158

Distributed by:
RUGBY LABORATORIES
17177 N Laurel Park Drive
Suite 233, Livonia, MI 48152
www.rugbylaboratories.com
Product of Italy



9690001
AK60107

3489

NDC 0536-1252-40

Rugby

Compare to the active ingredient in Zaditor*

Eye Itch Relief

ketotifen fumarate ophthalmic solution, 0.035%
ANTI-HISTAMINE EYE DROPS

UP TO
12
HOURS
EYE ITCH RELIEF

- **Works in Minutes**
- **Original Prescription Strength**
- **For Ages 3 Years and Older**

5mL
STERILE (0.17 FL OZ)

KETOTIFEN FUMARATE

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1252
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:0536-1252-40	1 in 1 CARTON	09/18/2020	
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
NDA authorized generic	NDA021996	09/18/2020	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(0536-1252) , PACK(0536-1252) , LABEL(0536-1252)

Revised: 9/2020

Rugby Laboratories