

EYE ITCH RELIEF- ketotifen fumarate solution/ drops

Rugby Laboratories

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 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 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?

1-800-645-2158

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

Principal Display Panel Text for Container Label:

Rugby® Logo

NDC 0536-1096-40

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:

Rugby® Logo NDC 0536-1096-40

Compare to the active

ingredient in Zaditor®*

Eye Itch

Relief

Ketotifen Fumarate

Ophthalmic Solution 0.035%

ANTIHISTAMINE EYE DROPS

UP TO

12

HOURS

ITCH RELIEF

- Works in minutes
- Original prescription strength

For ages 3 years and older

30-day supply

5 mL (0.17 FL OZ) STERILE



EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1096
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:0536-1096-40	1 in 1 CARTON	01/20/2016	
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	01/20/2016	

Labeler - Rugby Laboratories (079246066)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(0536-1096) , ANALYSIS(0536-1096) , STERILIZE(0536-1096) , PACK(0536-1096) , LABEL(0536-1096)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(0536-1096)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	LABEL(0536-1096) , PACK(0536-1096)