EYE ITCH- ketotifen fumarate solution/ drops
Kroger Company

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
- charges 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 (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?

1-800-632-6900

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

Principal Display Panel Text for Container Label:

NDC 30142-702-01

Kroger Logo®

STERILE

Eye Itch

Relief Drops

Ketotifen Fumarate

Ophthalmic Solution 0.035%

Antihistamine

Eye Drops 5 mL

(0.17 FL OZ)

Principal Display Panel Text for Carton Label:

COMPARE TO the active ingredient of

Zaditor® *See side panel

NDC 30142-702-01

Kroger Logo

ORIGINAL PRESCRIPTION STRENGTH

STERILE

Eye Itch

Relief Drops

Ketotifen Fumarate

Ophthalmic Solution 0.035%

Antihistamine Eye Drops

- Works in Minutes
- For Ages 3 Years and Older
- 30-Day Supply

LASTS UP TO
12

HOURS

5 mL

(0.17 FL OZ)

EYE ITCH

ketotifen fumarate solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-702
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:30142-702-01	1 in 1 CARTON	01/22/2014	
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	01/22/2014	

Labeler - Kroger Company (006999528)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(30142-702) , ANALYSIS(30142-702) , STERILIZE(30142-702) , PACK(30142-702) , LABEL(30142-702)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(30142-702)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	LABEL(30142-702) , PACK(30142-702)

Revised: 2/2022 Kroger Company