

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
- 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 (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)

The image shows the principal display panel text for the container label of Kroger Eye Itch Relief Drops. The label is divided into three main sections: a barcode section on the left, a central product information section, and a safety and directions section on the right.

Barcode Section (Left): A standard 1D barcode with the number 1701 below it. Below the barcode is the text "XKKZAAL Rev. 06/18".

Central Product Information Section: This section has an orange background with a geometric pattern. It features the Kroger logo at the top left. To the right of the logo is the text "NDC 30142-702-01". Below the logo is the text "STERILE Eye Itch Relief Drops". Underneath that is "Ketotifen Fumarate Ophthalmic Solution 0.035% Antihistamine Eye Drops". At the bottom right of this section is "5 mL (0.17 FL OZ)".

Safety and Directions Section (Right): This section has a white background. It starts with "ONLY FOR USE IN THE EYE" in bold, followed by "DO NOT USE IF IMPRINTED SEAL ON BOTTLE IS MISSING OR BROKEN". Below that is "Directions: Read detailed consumer information on box before using." and "Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]". At the bottom right is a 2D barcode with the number "(01)00330142702013" below it.

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)