

ITCHY EYE- ketotifen fumarate solution/ drops
Meijer Distribution Inc

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?

1-800-932-5676

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

Principal Display Panel Text for Container Label:

NDC 41250-303-01

Meijer™ Logo

Itchy Eye Drops

Ketotifen Fumarate Ophthalmic Solution 0.035%

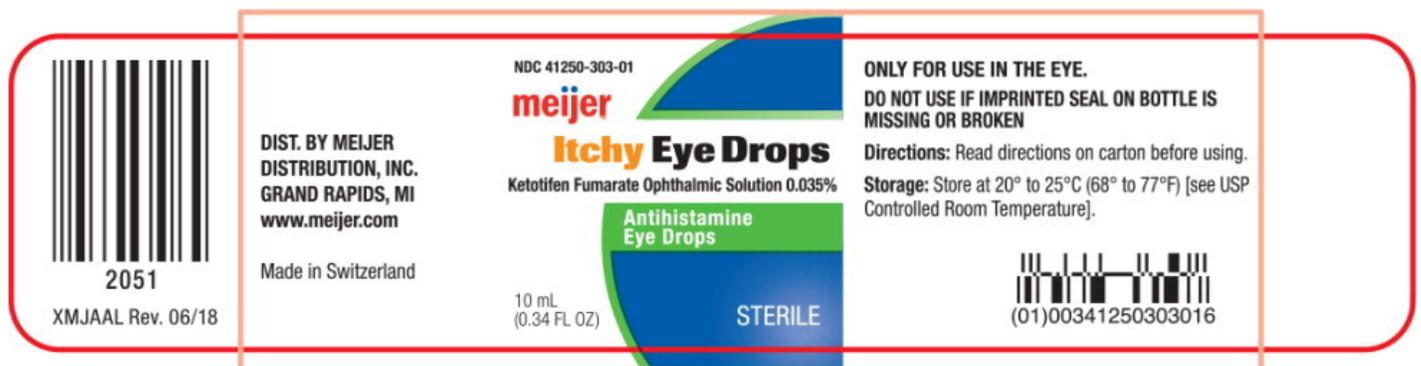
Antihistamine

Eye Drops

10 mL

0.34 FL OZ

STERILE



Principal Display Panel Text for Carton Label:

NDC 41250-303-01 Compare to Alaway®

active ingredient*

Meijer™ Logo

UP TO 12

HOURS OF RELIEF

Itchy Eye Drops

Ketotifen Fumarate Ophthalmic Solution 0.035%

Antihistamine Eye Drops

Works in Minutes

Original Prescription Strength

For ages 3 years and older

60-day supply

10 mL 0.34 FL OZ STERILE

meijer Itchy Eye Drops
Ketotifen Fumarate Ophthalmic Solution
Antihistamine Eye Drops



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Drug Facts (continued)

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DIST. BY MEIJER DISTRIBUTION, INC.
GRAND RAPIDS, MI
www.meijer.com
Made in Switzerland



NDC 41250-303-01

Compare to Alaway®
active ingredient*

meijer

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Itchy Eye Drops

Ketotifen Fumarate Ophthalmic Solution 0.035%

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60-day supply

10 mL (0.34 FL OZ)

STERILE

WARNING: KEEP OUT OF THE REACH OF CHILDREN

PRECAUTION: Do not touch dropper tip to any surface, as this may contaminate the solution. DO NOT USE IF IMPRINTED SEAL ON BOTTLE IS MISSING OR BROKEN



Actual size



fill level

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*This product is not manufactured or distributed by Bausch & Lomb, distributor of Alaway®.
XNJJAAC Rev. 06/18

ITCHY EYE

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-303
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: 059QF0K00R)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-303-01	1 in 1 CARTON	01/26/2016	
1		10 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	01/26/2016	

Labeler - Meijer Distribution Inc (006959555)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(41250-303) , ANALYSIS(41250-303) , STERILIZE(41250-303) , PACK(41250-303) , LABEL(41250-303)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(41250-303)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	LABEL(41250-303) , PACK(41250-303)

Revised: 2/2022

Meijer Distribution Inc