

KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops
Walgreens

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 for 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

Principal Display Panel Text for Container Label:

Walgreens Logo

Eye Itch Relief

KETOTIFEN FUMARATE
OPHTHALMIC SOLUTION /
ANTIHISTAMINE EYE DROPS

● Sterile

0.34 FL OZ (10 mL)



Principal Display Panel Text for Carton Label:

Walgreens Logo

Compare to Alaway® active ingredient††

Eye Itch

Relief

KETOTIFEN FUMARATE
OPHTHALMIC SOLUTION /
ANTIHISTAMINE EYE DROPS

WORKS IN MINUTES

- Original prescription strength
- Lasts for up to 12 hours
- 3 years & older
- Sterile

0.34 FL OZ (10 mL)

Walgreens

Eye Itch Relief

Walgreens

Compare to Alaway® active ingredient![†]

NDC 0383-9060-00

PHARMACIST RECOMMENDED

Walgreens
Trusted since 1901™

Health expertise you rely on.™

Eye Itch Relief

KETOTIFEN FUMARATE
OPHTHALMIC SOLUTION /
ANTIHISTAMINE EYE DROPS

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Drug Facts (continued)

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Questions or comments?
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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL ON BOTTLE IS MISSING OR BROKEN

[†]Walgreens Pharmacist Survey
[‡]This product is not manufactured or distributed by Bausch & Lomb, distributor of Alaway®.

DISTRIBUTED BY:
WALGREEN CO.
200 WILMOT RD.,
DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
walgreens.com
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Made in Switzerland

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Uses
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ITEM 230848 W/10160-0818-L

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XWGKTAC Rev. 06/18

ORG0518-F
REV 1018

KETOTIFEN FUMARATE

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9060
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)	
water (UNII: 059QF0K00R)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9060-00	1 in 1 CARTON	01/25/2013	
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	01/25/2013	

Labeler - Walgreens (008965063)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(0363-9060) , ANALYSIS(0363-9060) , STERILIZE(0363-9060) , PACK(0363-9060) , LABEL(0363-9060)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(0363-9060)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	LABEL(0363-9060) , PACK(0363-9060)

Revised: 2/2022

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