

ALAWAY PRESERVATIVE FREE- ketotifen fumarate solution/ drops
Bausch & Lomb Incorporated

Drug Facts

Active ingredient

Ketotifen 0.025% (equivalent to ketotifen fumarate 0.035%)

Purpose

Antihistamine

Uses

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
- discard unused portion immediately after use
- remove contact lenses before use
- does not include a preservative.

Stop use and ask a doctor if you experience any of the following:

- eye pain
- changes in vision
- redness of the eyes
- itching that 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:**
- twist tab completely off to open
- put 1 drop in the affected eye(s) twice daily, every 8-12 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 between 4-25 °C (39-77 °F).
- Use only if foil pouch is sealed and single-dose vial is intact.
- Store unused units in foil pouch.
- Protect from light.

Inactive ingredients

glycerin, hydrochloric acid and/or sodium hydroxide to adjust pH, and water for injection

Questions or comments?

[phone icon]Call Toll Free: 1-800-553-5340

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

Distributed by:

Bausch & Lomb Americas Inc.

Bridgewater, NJ 08807 USA

Product of Italy

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Package/Label Principal Display Panel

BAUSCH + LOMB

NDC 24208-600-01

Alaway®

Preservative Free

Ketotifen Fumarate Ophthalmic Solution 0.035%

ANTIHISTAMINE EYE DROPS

Eye Itch Relief

UP TO 12HOURS

Works in Minutes

Original Prescription Strength

For Ages 3 Years And Older

10 DAY SUPPLY

20 [4 pouches x five 0.4 mL] SINGLE-DOSE VIALS

Discard unused portion

STERILE

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10-009-8078 CDN
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Alaway[®] Preservative Free

Ketotifen Fumarate Ophthalmic Solution 0.035%
ANTHISTAMINE EYE DROPS

Eye Itch Relief

UP TO
12
HOURS

Directions

Single-use sterile dispenser



To open,
twist tab off.



Put 1 drop in the
affected eye(s) twice
daily, every 8-12 hours,
no more than twice per
day. Discard dispenser
immediately after use.

DO NOT USE IF POUCH IS TORN OR OPEN

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STERILE
Discard unused portion

Works in Minutes
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Eye Itch Relief

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Preservative Free
Ketotifen Fumarate Ophthalmic Solution 0.035%
ANTHISTAMINE EYE DROPS

BAUSCH + LOMB
NDC 24208-600-01

Eye Itch Relief
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Preservative Free
Ketotifen Fumarate Ophthalmic Solution 0.035%
ANTHISTAMINE EYE DROPS

ALAWAY PRESERVATIVE FREE

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24208-600
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
GLYCERIN (UNII: PDC6A3C00X)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24208-600-01	4 in 1 CARTON	09/24/2020	
1		5 in 1 POUCH		
1		0.4 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:24208-600-99	12 in 1 CARTON	09/24/2020	
2		1 in 1 POUCH		
2		0.4 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208158	09/24/2020	

Labeler - Bausch & Lomb Incorporated (196603781)

Establishment

Name	Address	ID/FEI	Business Operations
Excelvision		274234566	MANUFACTURE(24208-600)

Revised: 5/2022

Bausch & Lomb Incorporated