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

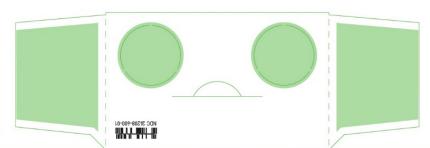
10 DAY SUPPLY

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

STERILE

9677202

622243



(01)00254508600016

Alaway. Preservative Free

Ketotifen Fumarate Ophthalmic Solution 0.035%

Eye Itch Relief







DO NOT USE IF POUCH IS TORN OR OPEN

Drug Facts

Active ingredient Purpose Ketotifen 0.025% (equivalent to ketotifen fumarate 0.035%).....Antihistamine

Uses Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.

Warnings For external use only

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Alaway. Preservative Free

Ketotifen Fumarate Ophthalmic Solution 0.035% ANTIHISTAMINE EYE DROPS

Eye Itch Relief



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For Ages 3 Years And Older Original Prescription Strength

Works in Minutes



Eye Itch Relief

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N DC 57508-900-01

BAUSCH-LOMB

DO NOT USE IF POUCH IS TORN OR OPEN Eye Itch Relief

Ketotifen fu marate Ophthalmic Solution O.D.35% Anthi stamwe eyeo Rops Preservative Free



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: PDC6A3C0OX)			
HYDROCHLORIC ACID (UNII: QTT17582CB)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
WATER (UNII: 059QF0KO0R)			

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