

**ALAWAY- ketotifen fumarate solution/ drops**  
**Bausch & Lomb Incorporated**

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**Drug Facts**

***Active ingredient***

Ketotifen 0.025%  
(equivalent to ketotifen fumarate 0.035%)

***Purpose***

Antihistamine

***Uses***

for the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.

***Warnings***

**For external use only**

**Do not use**

- if you are sensitive to any ingredient in this product
- if solution changes color or becomes cloudy
- to treat contact lens related irritation

**When using this product**

- remove contact lenses before use
- wait at least 10 minutes before re-inserting contact lenses after use
- do not touch tip of container to any surface to avoid contamination
- 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 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 and older:**
  - put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day
  - if using other ophthalmic products while using this product, wait at least 5 minutes between each product
- **children under 3 years of age:** consult a doctor

## ***Other information***

store at 4-25°C (39-77°F)

## ***Inactive ingredients***

benzalkonium chloride 0.01%, glycerin, hydrochloric acid and/or sodium hydroxide, water for injection

## ***Questions or comments?***

**Call: 1-800-553-5340**

## **Package/Label Principal Display Panel**

3480



BAUSCH + LOMB

**Alaway**

ketotifen fumarate  
ophthalmic solution 0.035%  
ANTIHISTAMINE EYE DROPS

DO NOT USE IF IMPRINTED BECKING IS "PROTECTIVE SEAL"  
WITH YELLOW IS NOT INDIC.



NDC 24208-601-10

NEW  
LOOK

NDC 24208-601-10

BAUSCH + LOMB

**Alaway**

ketotifen fumarate  
ophthalmic solution 0.035%  
ANTIHISTAMINE EYE DROPS

Eye Itch  
Relief

UP TO  
**12**  
HOURS

Works in Minutes

Original  
Prescription Strength

For Ages  
3 Years And Older

**60**

DAY SUPPLY

STERILE 0.34 FL OZ (10 mL)



Distributed by: Bausch + Lomb, a  
division of Bausch Health US, LLC  
Bridgewater, NJ 08807 USA  
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or its affiliates.

**60 DAY  
SUPPLY**

Fill Line

Actual Size

Order No. AB60109A

Product of Italy

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**Drug Facts (continued)**

- redness of the eyes
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injection

**Questions or comments?**

Call: 1-800-553-5340



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AB60109A



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**NEW  
LOOK  
NDC 24208-601-10  
BAUSCH + LOMB  
Alaway®**

ketotifen fumarate  
ophthalmic solution 0.035%

ANTI-HISTAMINE EYE DROPS

Eye Itch  
Relief

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For Ages  
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**60**  
**DAY SUPPLY**

STERILE 0.34 FL OZ (10 mL)

**ALAWAY**

ketotifen fumarate solution/ drops

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24208-601
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>KETOTIFEN FUMARATE</b> (UNII: HBD503WORO) (KETOTIFEN - UNII:X49220T18G)	KETOTIFEN	0.25 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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1	NDC:24208-601-10	1 in 1 CARTON	12/01/2006	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:24208-601-95	1 in 1 CARTON	12/01/2006	09/30/2015
2		1 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:24208-601-05	1 in 1 CARTON	12/01/2006	
3		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
4	NDC:24208-601-90	2 in 1 CARTON	12/01/2006	
4		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
NDA	NDA021996	12/01/2006	

**Labeler** - Bausch & Lomb Incorporated (196603781)

## Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(24208-601) , PACK(24208-601) , LABEL(24208-601)

Revised: 9/2021

Bausch & Lomb Incorporated