

EYE ITCH RELIEF- ketotifen fumarate solution

Cardinal Health

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?

[phone icon]Call: **1-877-758-1480**

Package/Label Principal Display Panel

LEADER[heart icon][™]

NDC 70000-0522-2

Sterile / Eye Drops

Eye Itch

Relief

ketotifen fumarate

ophthalmic solution 0.035%

ANTIHISTAMINE EYE DROPS

Up to 12 Hours

Works in Minutes

Original Prescription Strength

For Ages 3 Years and Older

COMPARE to

Systeme ZADITOR

active ingredient*

100% Money

Back Guarantee

0.34 FL OZ (10 mL) 9688902

3660



Sterile | Eye Drops
Eye Itch Relief
ketotifen fumarate
ophthalmic solution 0.035%
ANTIHISTAMINE EYE DROPS

NDC 70000-0522-2
Sterile | Eye Drops
Eye Itch Relief
ketotifen fumarate
ophthalmic solution 0.035%
ANTIHISTAMINE EYE DROPS

Up to 12 Hours
Works in Minutes
Original Prescription Strength
For Ages 3 Years and Older

Compare to Systane ZADITOR active ingredient*
100% Money Back Guarantee

0.34 FL OZ (10 mL)

DO NOT USE IF IMPRINTED NECKBAND "PROTECTIVE SEAL" WITH YELLOW IS NOT INTACT.
*This product is not manufactured or distributed by Alcon owner of the trademarks Systane and ZADITOR.
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Product of Italy
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CIN 5564349 REV. 11/23



Drug Facts (continued)
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FB60109

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EYE ITCH RELIEF
ketotifen fumarate solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0522	
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)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0522-1	1 in 1 CARTON	08/07/2020	
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0522-2	1 in 1 CARTON	08/07/2020	
2		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA021996	08/07/2020		

Labeler - Cardinal Health (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(70000-0522) , PACK(70000-0522) , LABEL(70000-0522)