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 (1-800-222-1222) 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.
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] Toll Free Product Information
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
ZADITOR®
active ingredient

100% Money
Back Guarantee

0.34 FL OZ (10 mL)

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)

Revised: 6/2021 Cardinal Health