

EYE ITCH RELIEF- ketotifen fumarate solution/ drops
CVS Pharmacy

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.

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: 1-866-767-9161

Package/Label Principal Display Panel

[heart icon] **CVS**

Health

NDC 69842-275-10

Eye Itch

Relief

ketotifen fumarate

ophthalmic solution 0.035%

ANTIHISTAMINE EYE DROPS

- Works in minutes
- Original prescription strength
- For ages 3 years & older
- 60-day supply

UP TO

12

HOURS

EYE ITCH

RELIEF

Package Contains

One Bottle

STERILE

0.034 FL OZ (10 mL)

3538



3538

EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-275
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:69842-275-10	1 in 1 CARTON	04/01/2020	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:69842-275-05	1 in 1 CARTON	04/01/2020	
2		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:69842-275-20	2 in 1 CARTON	04/01/2020	
3		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	04/01/2020	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	manufacture(69842-275)