EYE ITCH RELIEF- ketotifen fumarate solution CVS Pharmacy

CVS Pharmacy, Inc. Eye Itch Relief 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

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
- remove contact lenses before use
- wait at least 10 minutes before reinserting contact lenses after use
- 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 eye
- itching 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. (1-800-222-1222)

Directions

• Adults and children 3 years of age 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

- only for use in the eye
- store at 20-25°C (68-77°F) [see USP Controlled Room Temperature]

Inactive ingredients

benzalkonium chloride 0.01%, glycerin, purified water. May contain hydrochloric acid and/or sodium hydroxide (to adjust pH).

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredient in Zaditor®

EYE ITCH RELIEF

KETOTIFEN FUMARATE OPHTHALMIC SOLUTION

ANTIHISTAMINE EYE DROPS

Original prescription strength

For ages 3 yrs. and older

30 day supply

GET UP TO 12 HOURS OF RELIEF

Sterile







Drug Facts

Active ingredient

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Stop use and ask a doctor if you experience any of the following: ■ eye pain
■ changes in vision ■ redness of the eye

- itching worsens or lasts for more than 72 hours
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Drug Facts (continued) Inactive ingredients

benzalkonium chloride 0.01% alycerin, purified water. May contain hydrochloric acid and/or sodium hydroxide (to adjust pH).

(Questions or comments? 1-800-719-9260

NECKBAND IS BROKEN OR MISSING

FOR TOPICAL OPHTHALMIC **USE ONLY**

WARNING - KEEP OUT OF THE REACH OF CHILDREN

PRECAUTION: Do not touch dropper tip to any surface, as this may contaminate the solution.

This product is not manufactured or distributed by Novartis, distributor of Zaditor®,

Distributed by:

CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895 © 2012 CVS/pharmacy





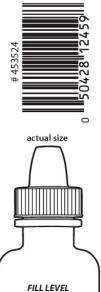
NDC 59779-982-01

Compare to the active ingredient in Zaditor®

ANTIHISTAMINE EYE DROPS

- Original prescription strength
- For ages 3 yrs. and older
- · 30 day supply





NDC:59779-982

Sterile

5 mL (0.17 FL OZ)





LOT NO.

EXP.

: 923CA 17 C3

DEA Schedule

EYE ITCH RELIEF

ketotifen fumarate solution

Product Information

Route of Administration

Product Type HUMAN OTC DRUG LABEL Item Code (Source)

OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength KETOTIFEN FUMARATE (KETOTIFEN) KETOTIFEN $0.25\,\mathrm{g}$ in $1\,\mathrm{mL}$

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN	
WATER	
HYDRO CHLO RIC ACID	
SO DIUM HYDRO XIDE	

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:59779-982-01	1 in 1 CARTON					
1		5 mL in 1 BOTTLE					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA077958	09/14/2010				

Labeler - CVS Pharmacy (062312574)

Revised: 4/2013 CVS Pharmacy