EYE ITCH RELIEF- ketotifen fumarate solution
Safeway

Drug Facts

Active ingredient

Ketotifen 0.025%

Purpose

Antihistamine

(equivalent to ketotifen fumarate 0.035%)

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 and water for injection.

Questions?

Call: 1-800-553-5340

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

Package/Label Principal Display Panel – 5mL carton

NDC 21130-601-05

***Signature*™**
Care

Quality Guaranteed

STERILE
ORIGINAL PRESCRIPTON STRENGTH

Eye Itch Relief
ketotifen fumarate
ophthalmic solution 0.035%
Antihistamine Eye Drops

Compare to the active ingredient in Zaditor*

Up to 12 hours

0.17 FL OZ (5mL)

EYE ITCH RELIEF

ketotifen fumarate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21130-601
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:21130-601-05	1 in 1 CARTON	08/20/2014	
1		5 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	08/20/2014	

Labeler - Safeway (009137209)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(21130-601)

Revised: 1/2020 Safeway