EYE ITCH RELIEF- ketotifen fumarate solution/ drops
TOPCO ASSOCIATES LLC

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: **1-888-423-0139**

Package/Label Principal Display Panel

NDC 36800-097-05

+Top Care™

health

COMPARE TO Systane ZADITOR

active ingredient*

Eye Itch Relief

ketotifen fumarate

ophthalmic solution 0.035%

ANTIHISTAMINE

EYE DROPS UPTO

12

HOURS

- Works in Minutes
- Original Prescription Strength
- For Ages 3 Years and Older

STERILE 0.17FL OZ (5 mL)

9756901

FT60107

EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-097

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:36800-097-05	1 in 1 CARTON	03/15/2022	
1		5 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	03/15/2022	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(36800-097)

Revised: 12/2023 TOPCO ASSOCIATES LLC