KETOTIFEN FUMARATE- ketotifen fumarate solution
Strategic Sourcing Services LLC

Drug Facts

Active ingredient

Ketotifen (0.025%)

(equivalent to ketotifen fumarate 0.035%)

Purpose

Antihistamine

Use

Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.

Warnings

For external use only

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.

Directions

- **Adults and children 3 years of age and older:** Put 1 drop in the affected eye(s) twice daily, every 8 to 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°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].

Inactive ingredients

benzalkonium chloride 0.01%, glycerol, hydrochloric acid and/or sodium hydroxide, and water for injection

Questions or comments?

call us at **1-800-706-5575** (Monday to Friday 8:30 am – 5:00 pm Eastern Standard Time)

Principal Display Panel - Bottle Label

McKesson - SunMark

NDC 70677-0052-1

Ketotifen Fumarate Opthalmic Solution 0.025% 5 ml bottle

Principal Display Panel - Bottle Carton

McKesson - SunMark

NDC 70677-0052-1

Ketotifen Fumarate Opthalmic Solution 0.025% 5 ml bottle

KETOTIFEN FUMARATE

ketotifen fumarate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70677-0052
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**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70677-0052-1	1 in 1 CARTON	06/18/2019	
1		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077354	06/18/2019	

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 9/2019 Strategic Sourcing Services LLC