

EYE ITCH RELIEF- ketotifen fumarate solution/ drops
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 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 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° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Inactive ingredients

Benzalkonium Chloride 0.01%, Glycerin, Water for Injection.

May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

Questions or comments?

1-800-923-5676

Serious side effects associated with use of this product may be reported to this number

Principal Display Panel Text for Container Label:

Sunmark Logo®

NDC 49348-107-17

sterile

eye itch relief

ketotifen fumarate

ophthalmic solution 0.035%

Antihistamine Eye Drops

5 mL (0.17 FL OZ)



Principal Display Panel Text for Carton Label:

Sunmark Logo®

COMPARE TO ZADITOR®

ACTIVE INGREDIENT*

NDC 49348-107-17

sterile

eye itch

relief

ketotifen fumarate

ophthalmic

solution 0.035%

Antihistamine Eye Drops

For ages 3 years and older

30-day supply

Works in minutes

Original Prescription Strength

UP TO 12 HOURS OF RELIEF

5 mL (0.17 FL OZ)



EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-107
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ketotifen fumarate (UNII: HBD503WORO) (Ketotifen - UNII:X49220T18G)	Ketotifen	0.35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
benzalkonium chloride (UNII: F5UM2KM3W7)	
glycerin (UNII: PDC6A3C0OX)	
water (UNII: 059QF0KO0R)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-107-17	1 in 1 CARTON	02/07/2014	
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
ANDA	ANDA077958	02/07/2014	

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(49348-107) , ANALYSIS(49348-107) , STERILIZE(49348-107) , PACK(49348-107) , LABEL(49348-107)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(49348-107)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	LABEL(49348-107) , PACK(49348-107)