KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops
REMEDYREPACK INC.

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

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 8-12 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 and Purified Water. May contain Hydrochloric Add and/or Sodium Hydroxide (to adjust pH).

Questions?

call toll-free **1-800-932-5676,** weekdays, 7:00 AM - 5:30 PM CST

DRUG: Ketotifen Fumarate

GENERIC: Ketotifen Fumarate

DOSAGE: SOLUTION/ DROPS

ADMINSTRATION: OPHTHALMIC

NDC: 70518-1142-0

PACKAGING: 5 mL in 1 BOTTLE, DROPPER

OUTER PACKAGING: 1 in 1 CARTON

ACTIVE INGREDIENT(S):

- ketotifen fumarate 0.35mg in 1mL

INACTIVE INGREDIENT(S):

- benzalkonium chloride
- hydrochloric acid
- sodium hydroxide
- glycerin
- water

Ketotifen Fumarate

0.025%

0.35mg/ 1mL Ophth Solu

QTY: 5

ID #: .

NDC #: 70518-1142-00

LOT #:

MFG: Akorn, Lake Forest, IL 60045

NOT FOR RETAIL SALE

Expires:

Shape: .

Ref #: 17478-0717-10

Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by:
RemedyRepack Inc., Indiana, PA 15701, 1-724-465-8762

KETOTIFEN FUMARATE

ketotifen fumarate solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70518-1142(NDC:17478-717)
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:70518-1142-0	1 in 1 CARTON	04/27/2018	
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	04/27/2018	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 8/2019 REMEDYREPACK INC.