KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops
Akorn, 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

Principal Display Panel Text for Container Label:

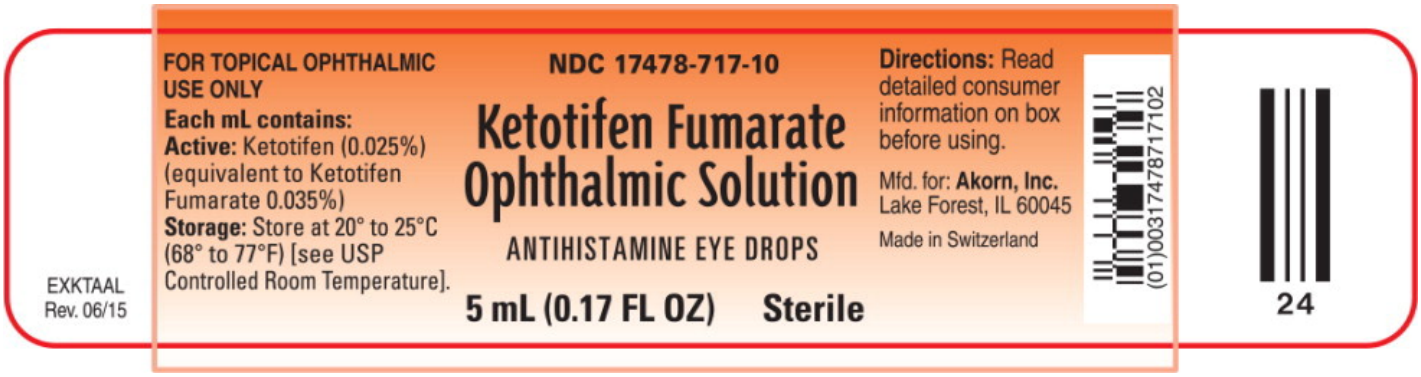
NDC 17478-717-10

Ketotifen Fumarate

Ophthalmic Solution

ANTIHISTAMINE EYE DROPS

5 mL (0.17 FL OZ) Sterile



Principal Display Panel Text for Carton Label:

Now OTC! NDC 17478-060-12

Akorn Logo

Ketotifen

Fumarate

Ophthalmic

Solution

ANTIHISTAMINE EYE DROPS

UP TO 12 HOURS EYE ITCH RELIEF

Works in Minutes

Original Prescription Strength

FOR AGES 3 YEARS AND OLDER

30 DAY SUPPLY

5 mL (0.17 FL OZ) Sterile

KETOTIFEN FUMARATE

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:17478-717-10	1 in 1 CARTON	10/01/2007	
1		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:17478-717-11	1 in 1 CARTON	09/30/2016	
2		10 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	10/01/2007	

Labeler - Akorn, Inc. (062649876)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(17478-717) , ANALYSIS(17478-717) , PACK(17478-717) , LABEL(17478-717)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		603980319	MANUFACTURE(17478-717) , REPACK(17478-717) , ANALYSIS(17478-717) , LABEL(17478-717) , PACK(17478-717) , RELABEL(17478-717) , STERILIZE(17478-717)