# **KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops Walgreens**

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**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 eve
- 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 8-12 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%, glycerin, purified water. May contain hydrochloric acid and/or sodium hydroxide (to adjust pH).

#### Questions or comments?

1-800-579-8327

Principal Display Panel Text for Container Label:

Well at

Walgreens NDC 0363-9060-00

STERILE • ORIGINAL

PRESCRIPTION STRENGTH

Eye Itch Relief

Ketotifen Fumarate

Ophthalmic Solution

Antihistamine Eye Drops 0.34 FL OZ (10 mL)



Principal Display Panel Text for Carton Label:

Well at

Walgreens NDC 0363-9060-00

WALGREENS PHARMACIST RECOMMENDED≠

STERILE • ORIGINAL

PRESCRIPTION STRENGTH

Eye Itch

Relief

Ketotifen Fumarate

Ophthalmic Solution

Antihistamine Eye Drops

• Works in minutes

- For ages 3 years & older
- 60-day supply

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**HOUR** 

0.34 FL OZ (10 mL)



#### KETOTIFEN FUMARATE

ketotifen fumarate solution/ drops

#### **Product Information**

Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:0363-9060

Route of Administration	OPHTHALMIC	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ketotifen fumarate (Ketotifen)	Ketotifen	0.35 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
benzalkonium chloride	
glycerin	
water	
hydrochloric acid	
sodium hydroxide	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9060-00	1 in 1 CARTON		
1		10 mL in 1 BOTTLE, DROPPER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077958	0 1/25/20 13	

## Labeler - Walgreens (008965063)

## **Registrant -** Akorn, Inc. (062649876)

Establishment			
Name	Address	ID/FEI	Business Operations
Akorn, Inc		603980319	MANUFACTURE(0363-9060), ANALYSIS(0363-9060), STERILIZE(0363-9060), PACK(0363-9060), LABEL(0363-9060)

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