

EYE ITCH RELIEF- ketotifen fumarate solution/ drops

Good Sense

Drug Facts

Active ingredient

Ketotifen (0.025%)

(equivalent to ketotifen fumarate 0.035%)

Purpose

Antihistamine

Uses

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 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° to 25°C (68° 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?

1-866-696-0957

Principal Display Panel Text for Container Label:

NDC 50804-302-01

GOODSENSE® Logo

Eye Itch Relief

Ketotifen Fumarate

Ophthalmic Solution

Antihistamine Eye Drops

0.17 FL OZ (5 mL) Sterile



Principal Display Panel Text for Carton Label:

NDC 50804-302-01

GOODSENSE® Logo

Works in Minutes

Eye Itch

Relief

Ketotifen Fumarate

Ophthalmic Solution

Antihistamine Eye Drops

Up To 12 Hours Itch Relief

- For Ages 3 Years and Older
- 30 Day Supply

Original Prescription Strength

Compare to active ingredient of 100%
 Zaditor®* SATISFACTION
 GUARANTEED
 0.17 FL OZ (5 mL) Sterile

GOODSENSE. Eye Itch Relief
 Ketotifen Fumarate Ophthalmic Solution/Antihistamine Eye Drops

NDC 50804-302-01

GOODSENSE. Works in Minutes

Eye Itch Relief

Ketotifen Fumarate Ophthalmic Solution
Antihistamine Eye Drops

Up To 12 Hours Itch Relief

- For Ages 3 Years and Older
- 30 Day Supply

Original Prescription Strength

Compare to active ingredient of Zaditor®* 100% SATISFACTION GUARANTEED

0.17 FL OZ (5 mL) Sterile

Drug Facts (continued)

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PGSZAAC Rev. 04/14

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DO NOT USE IF IMPRINTED SEAL ON BOTTLE IS MISSING OR BROKEN

*This product is not manufactured or distributed by Alcon Laboratories, distributor of Zaditor®.

Distributed By:
 Geiss, Destin & Dunn, Inc
 Peachtree City, GA 30269
 www.valuelabels.com

ACTUAL SIZE

FILL LEVEL

EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-302
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:50804-302-01	1 in 1 CARTON		
1		5 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077958	06/20/2014	

Labeler - Good Sense (076059836)**Registrant** - Akorn, Inc. (062649876)**Establishment**

Name	Address	ID/FEI	Business Operations
Akorn, Inc		603980319	MANUFACTURE(50804-302) , ANALYSIS(50804-302) , STERILIZE(50804-302) , PACK(50804-302) , LABEL(50804-302)

Revised: 6/2014

Good Sense