EYE ITCH RELIEF- ketotifen fumarate solution/ drops
Cardinal Health

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 the tip of container to any surface to avoid contamination
- remove contact lenses before use
- wait at least 10 minutes before reinserting contact lens 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, Water for Injection. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

Questions or comments?

1-800-932-5676

Principal Display Panel Text for Container Label:

LEADER™ Logo

NDC 70000-0124-1

Sterile

Eye Itch

Relief

Ketotifen Fumarate Ophthalmic Solution

Antihistamine Eye Drops

5 mL (0.17FL OZ)

Principal Display Panel Text for Carton Label:

LEADER™ Logo

NDC 70000-0124-1

Sterile

Eye Itch

Relief

Ketotifen Fumarate Ophthalmic Solution

Antihistamine Eye Drops

Up to 12 Hours

of Itch Relief COMPARE TO

Works in Minutes ZADITOR®

Original Prescription ANTIHISTAMINE

Strength EYE DROPS

Active ingredient*

For Ages 3 Years

& Older 100% Money

30-day Supply Back Guarantee

5 mL (0.17 FL OZ)

EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0124

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:70000-0124-1	1 in 1 CARTON	01/18/2017	
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	01/18/2017	

Labeler - Cardinal Health (097537435)

Registrant - Akorn, Inc. (062649876)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc		603980319	MANUFACTURE(70000-0124) , ANALYSIS(70000-0124) , STERILIZE(70000-0124) , PACK(70000-0124) , LABEL(70000-0124)

Revised: 1/2017 Cardinal Health