EYE ITCH RELIEF- ketotifen fumarate solution/ drops
H E B

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?

1-800-932-5676

Principal Display Panel Text for Container Label:

H ■ E ■ B Logo®

NDC 37808-802-01

Eye Itch

Relief

Ketotifen Fumarate

Ophthalmic Solution

Antihistamine Eye Drops

STERILE 5 mL (0.17 FL OZ)

Principal Display Panel Text for Carton Label:

NDC 37808-802-01 Compare to

the active

ingredients

in Zaditor®*

H ■ E ■ B Logo®

Eye Itch
Relief
Ketotifen Fumarate
Ophthalmic Solution
Antihistamine Eye Drops
Eye Drops
• Works in
Minutes
• Original
Prescription
Strength
• For ages
3 years
& Older
UP TO
12
HOURS
ITCH RELIEF
STERILE 5 mL (0.17 FL OZ)

EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37808-802
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:37808-802-01	1 in 1 CARTON	02/25/2014	
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	02/25/2014	

Labeler - H E B (007924756)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(37808-802) , ANALYSIS(37808-802) , STERILIZE(37808-802) , PACK(37808-802) , LABEL(37808-802)

Revised: 1/2022 H E B