KETOTIFEN FUMARATE- ketotifen fumarate solution
Bayshore Pharmaceuticals, LLC

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

For external use only

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 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°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].

Inactive ingredients

benzalkonium chloride 0.01%, glycerol, water for injection, sodium hydroxide and/or hydrochloric acid.

Questions?

Call Product Information at 973-315-1818. Serious side effects associated with use of this product may be reported to this number.

Code No.: GO/DRUGS/557

Manufactured For:
Bayshore Pharmaceuticals
LLC., Short Hills, NJ 07078
Made in India.

Principal Display Panel - Bottle Label

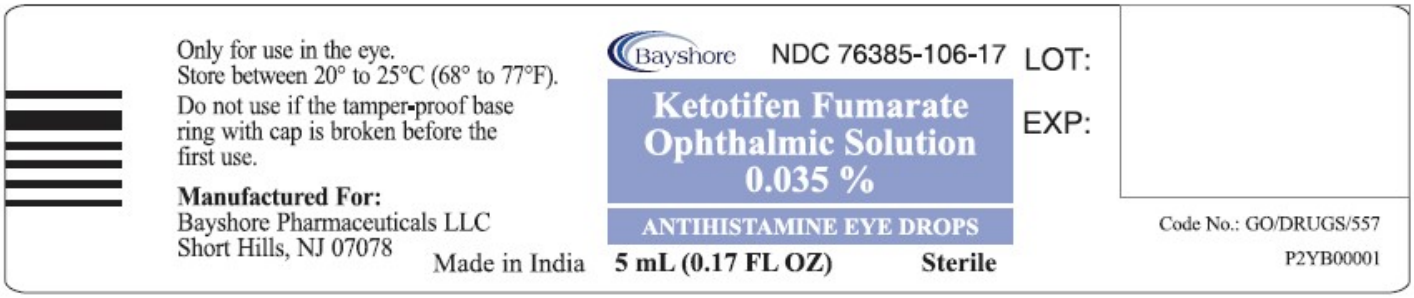
NDC 76385-106-17

Ketotifen Fumarate Opthalmic Solution 0.035%

ANTIHISTAMINE EYE DROPS

5 mL (0.17 FL OZ)

Sterile



Principal Display Panel - Bottle Carton

NDC 76385-106-17

Now OTC

Ketotifen Fumarate Opthalmic Solution 0.035%

ANTIHISTAMINE EYE DROPS

UP TO 12 HOURS

Eye Itch Relief

Works in Minutes

Original Prescription Strength

for ages 3 years and older

20 day supply

5 mL (0.17 FL OZ)

Sterile

KETOTIFEN FUMARATE

ketotifen fumarate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76385-106
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
KETOTIFEN FUMARATE (UNII: HBD503WORO) (Ketotifen - UNII:X49220T18G)	Ketotifen	0.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76385-106-17	1 in 1 CARTON	10/15/2021	
1		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204059	10/15/2021	

Labeler - Bayshore Pharmaceuticals, LLC (968737416)

Revised: 10/2021 Bayshore Pharmaceuticals, LLC