

KETOTIFEN FUMARATE- ketotifen fumarate solution
Unichem Pharmaceuticals (USA), Inc.

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 1-866-562-4616. Serious side effects associated with use of this product may be reported to this number.

Made in India

Distributed by:

UNICHEM PHARMACEUTICALS (USA), INC.

East Brunswick, NJ 08816 USA

Rev. 11/2025

KFO1236

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 76385-106-17

Ketotifen Fumarate Ophthalmic Solution 0.035%

ANTI HISTAMINE EYE DROPS

5 mL (0.17 FL OZ)

Sterile

Only for use in the eye.
Store between 20° to 25°C (68° to 77°F).
Do not use if the tamper-proof base ring with cap is broken before the first use.
Made in India.
Distributed by:
UNICHEM PHARMACEUTICALS (USA), INC.
East Brunswick, NJ 08816 USA.

NDC 76385-106-17 Sawgrass pharma LOT:
Ketotifen Fumarate EXP:
Ophthalmic Solution
0.035 %
ANTI HISTAMINE EYE DROPS 
5 mL (0.17 FL OZ) Sterile Rev. 11/2025 KFO1235

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 76385-106-17

Now OTC

Ketotifen Fumarate Ophthalmic Solution 0.035%

ANTI HISTAMINE 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 - Unichem Pharmaceuticals (USA), Inc. (181620514)

Registrant - Unichem Laboratories Limited, India (650055882)

Establishment

Name	Address	ID/FEI	Business Operations
Indoco Remedies Limited		915851870	ANALYSIS(76385-106) , LABEL(76385-106) , MANUFACTURE(76385-106) , PACK(76385-106)

