

**KETOTIFEN FUMARATE OPHTHALMIC SOLUTION- ketotifen fumarate solution/
drops**

Armas Pharmaceuticals Inc.

Ketotifen Fumarate Ophthalmic Solution

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

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 8-12 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 and Water for Injection. May contain Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH).

Questions?

call toll-free **1-855-473-6847**, weekdays, 7:00 AM - 5:30 PM CT

Now OTC!

ANTIHISTAMINE EYE DROPS

UPTO 12 HOURS EYE ITCH RELIEF

- **Works in Minutes**
- **Original Prescription Strength**

**FOR AGES 3 YEARS AND OLDER
30 DAY SUPPLY**

Sterile

Original Prescription Strength

Do not use if seal on bottle is missing or broken.

FOR TOPICAL OPHTHALMIC USE ONLY.

PRECAUTION: Do not touch dropper tip to any surface, as this may contaminate the solution.

**Distributed by: Armas Pharmaceuticals, Inc.
Freehold, NJ 07728 (USA)**

**Manufactured by: Ophtapharm AG, Riethofstrasse 1,
Hettlingen, 8442, Switzerland (CHE) for Sentiss**

Made in Switzerland

Packaging

INNER LABEL

FOR TOPICAL OPHTHALMIC USE ONLY

NDC 72485-617-10

Directions: Read detailed consumer information on box before using.

Distributed by: Armas Pharmaceuticals, Inc. Freehold, NJ 07728 (USA)

Made in Switzerland EXKTAAL Rev. 06/23

5 mL (0.17 FL OZ) Sterile

Ketotifen Fumarate Ophthalmic Solution

ANTIHISTAMINE EYE DROPS

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OUTER LABEL

Now OTC! NDC 72485-617-10

Ketotifen Fumarate Ophthalmic Solution

ANTIHISTAMINE EYE DROPS

UP TO 12 HOURS EYE ITCH RELIEF

◆ Works in Minutes

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FOR AGES 3 YEARS AND OLDER
30 DAY SUPPLY

5 mL (0.17 FL OZ) Sterile

SENTISS

Armas Pharmaceuticals

Original Prescription Strength

Up to 12 Hour Itch Relief

30 Day Supply

Works in Minutes

For Ages 3 Years and Older

EXKTAAC Rev. 06/23

Drug Facts (continued)

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3 7 2 4 8 5 1 6 1 7 1 0 4

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KETOTIFEN FUMARATE OPHTHALMIC SOLUTION

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72485-617
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

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:72485-617-10	1 in 1 CARTON	10/09/2023	
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	10/09/2023	

Labeler - Armas Pharmaceuticals Inc. (098405973)

Registrant - SENTISS AG (486920486)

Revised: 1/2024

Armas Pharmaceuticals Inc.