**KETOTIFEN FUMARATE OPHTHALMIC SOLUTION- ketotifen fumarate solution/ drops**
**Sentiss Pharmaceuticals LLC**

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**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.**

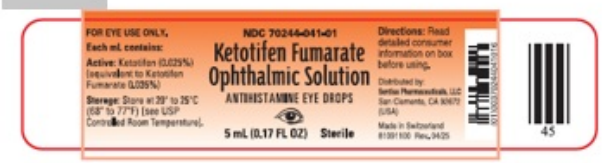
**Distributed by: Sentiss Pharmaceuticals, LLC**
**San Clemente, CA 92672 (USA)**

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

**Made in Switzerland**

**Packaging**

INNER LABEL




OUTER LABEL


# KETOTIFEN FUMARATE OPHTHALMIC SOLUTION

ketotifen fumarate solution/ drops

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:70244-041 |
| **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:70244-041-01 | 1 in 1 CARTON | 04/15/2026 | |
| 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 | 04/15/2026 | |

## Labeler - Sentiss Pharmaceuticals LLC (079621784)

## Registrant - SENTISS AG (486920486)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Ophtapharm AG | | 482198285 | analysis(70244-041) , label(70244-041) , manufacture(70244-041) , pack(70244-041) |

Revised: 4/2026 Sentiss Pharmaceuticals LLC