**EYE ITCH RELEIF- ketotifen fumarate solution/ drops**
**Rite Aid Corporation**

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**Drug Facts**

***Active ingredient***

Ketotifen 0.025%
(equivalent to ketotifen fumerate 0.035%)

***Purpose***

Antihistamine

***Uses***

for the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.

***Warnings***

**For external use only**

**Do not use**

- if you are sensitive to any ingredient in this product
- if solution changes color or becomes cloudy
- to treat contact lens related irritation

**When using this product**

- remove contact lenses before use
- wait at least 10 minutes before re-inserting contact lenses after use
- do not touch tip of container to any surface to avoid contamination
- 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 eyes
- itching that 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 and older:**

- put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day
- if using other ophthalmic products while using this product, wait at least 5 minutes between each product

- **children under 3 years of age:**consult a doctor

### *Other information*

store at 4-25 °C (39-77 °F)

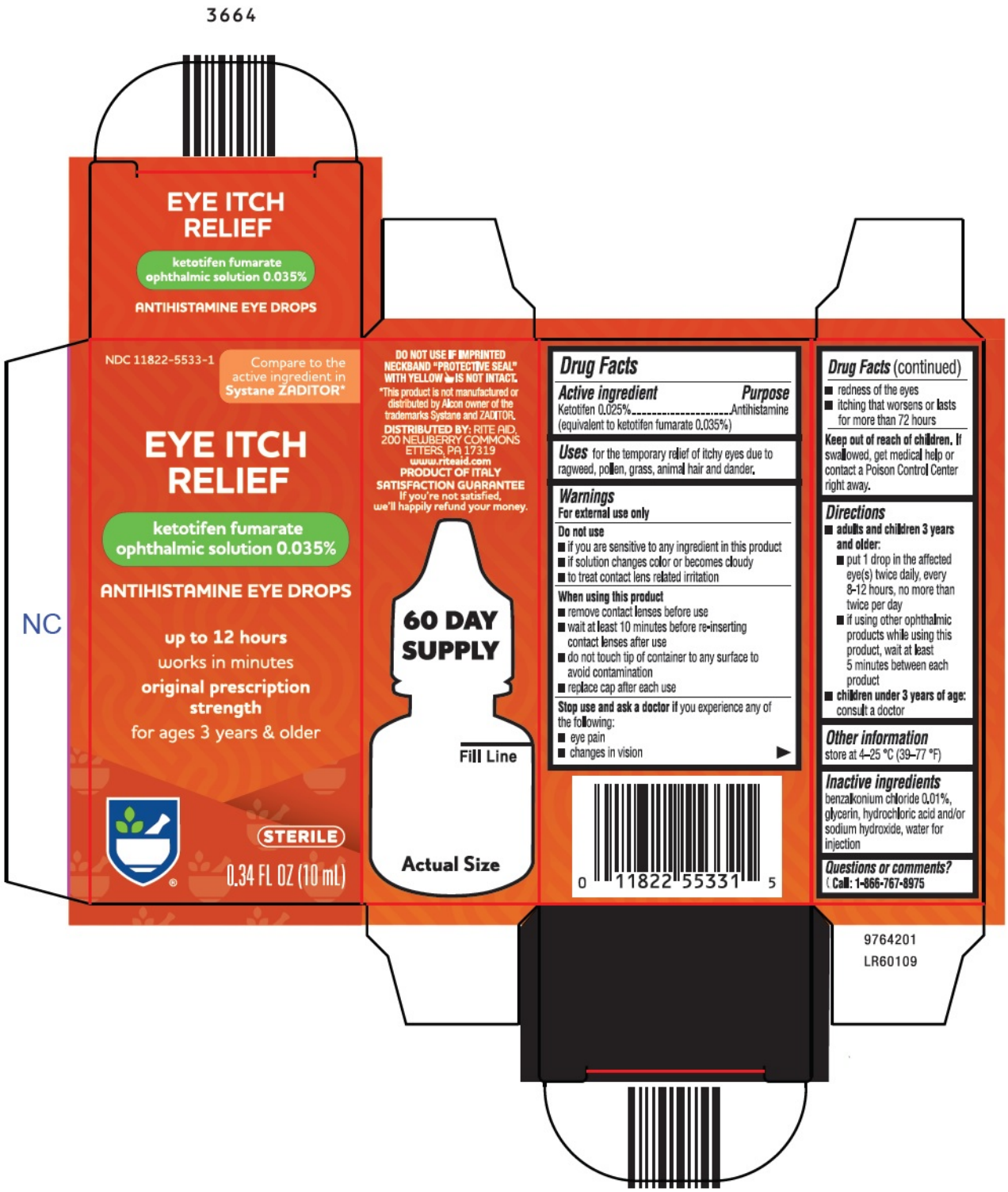
### *Inactive ingredients*

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

### *Questions or comments?*

[phone icon] **Call: 1-866-767-8975**

**Package/Label Principal Display Panel**




NDC 11822-5533-1

Compare to the

active ingredient in

**SystaneZaditor***

**EYE ITCH**

**RELIEF**

ketotifen fumarate
ophthalmic solution 0.035%

**ANTIHISTAMINE EYE DROPS**

**up to 12 hours**
works in minutes
**Original prescription strength**
for ages 3 years and older

**STERILE**
0.34 FL OZ (10 mL)

9764201

LR60109

# EYE ITCH RELEIF

ketotifen fumarate solution/ drops

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:11822-5533 |
| **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) | |
| **HYDROCHLORIC ACID** (UNII: QTT17582CB) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:11822-5533-1 | 1 in 1 CARTON | 04/01/2022 | |
| **1** | | 10 mL in 1 BOTTLE, DROPPER; Type 0: Not a | | |

| | | | | |
|---|---|---|---|---|
| 1 | | Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| NDA | NDA021996 | 04/01/2022 | |

## Labeler - Rite Aid Corporation (014578892)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Bausch & Lomb Incorporated | | 079587625 | manufacture(11822-5533) , pack(11822-5533) , label(11822-5533) |

Revised: 7/2024 Rite Aid Corporation