

**EYE ITCH RELIEF- ketotifen fumarate solution/ drops  
PERRIGO DIRECT INC.**

-----  
**Drug Facts**

***Active ingredient***

Ketotifen 0.025%  
(equivalent to ketotifen fumarate 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: 1-833-354-4500**

### **Package/Label Principal Display Panel**



**GOODSENSE®** NDC 50804-601-05

For ages 3 years and older

**Eye Itch Relief**

ketotifen fumarate

ophthalmic solution 0.035%

ANTIHISTAMINE EYE DROPS

Up to **12**hours

works in minutes

Original Prescription Strength

Compare to active ingredient of

Systane ZADITOR\*

STERILE 0.17 FL OZ (5 ml)

9797500

MH60107

## EYE ITCH RELIEF

ketotifen fumarate solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50804-601
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>KETOTIFEN FUMARATE</b> (UNII: HBD503WORO) (KETOTIFEN - UNII:X49220T18G)	KETOTIFEN	0.25 mg in 1 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:50804-601-05	1 in 1 CARTON	04/01/2024	
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
NDA	NDA021996	04/01/2024	

**Labeler** - PERRIGO DIRECT INC. (076059836)

## Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	manufacture(50804-601)

Revised: 1/2026

PERRIGO DIRECT INC.