

EYE ITCH RELIEF- ketotifen fumarate solution

Safeway

Drug Facts

Active ingredient

Ketotifen 0.025%

Purpose

Antihistamine

(equivalent to ketotifen fumarate 0.035%)

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?

{Phone icon} **Call: 1-800-459-7043**

*This product is not manufactured or distributed by Alcon owner of the trademarks Systane and ZADITOR.

Package/Label Principal Display Panel - 5mL carton

Compare to

Systane ZADITOR

active ingredient*

NDC 21130-601-05

Signature

SELECT®

Eye Itch Relief

ketotifen fumarate

ophthalmic solution 0.035%

ANTIHISTAMINE EYE DROPS

Up to 12 hours

Works in minutes

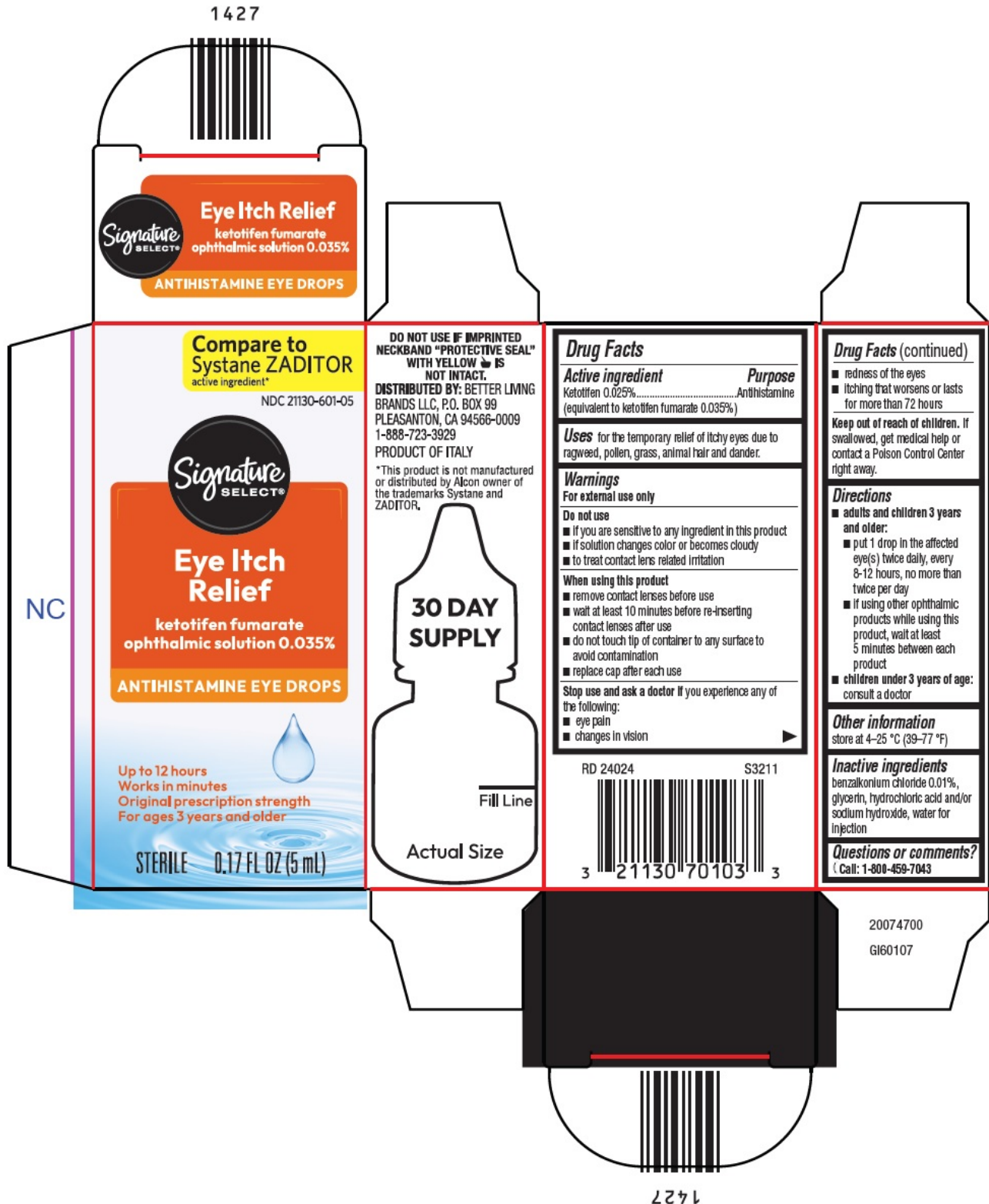
Original prescription strength

For ages 3 years and older

STERILE 0.17 FL OZ (5 mL)

20074700

GI60107



1427

Signature SELECT
Eye Itch Relief
ketotifen fumarate
ophthalmic solution 0.035%
ANTIHISTAMINE EYE DROPS

Compare to Systane ZADITOR
active ingredient*

NDC 21130-601-05

Signature SELECT

Eye Itch Relief
ketotifen fumarate
ophthalmic solution 0.035%
ANTIHISTAMINE EYE DROPS

Up to 12 hours
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STERILE 0.17 FL OZ (5 mL)

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DO NOT USE IF IMPRINTED NECKBAND "PROTECTIVE SEAL" WITH YELLOW IS NOT INTACT.
DISTRIBUTED BY: BETTER LIVING BRANDS LLC, P.O. BOX 99 PLEASANTON, CA 94566-0009 1-888-723-3929
PRODUCT OF ITALY

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30 DAY SUPPLY

Fill Line

Actual Size

Drug Facts

Active ingredient Ketotifen 0.025% Antihistamine (equivalent to ketotifen fumarate 0.035%)
Purpose Antihistamine

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■ changes in vision

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Drug Facts (continued)

■ redness of the eyes
■ itching that worsens or lasts for more than 72 hours

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Questions or comments?

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EYE ITCH RELIEF

ketotifen fumarate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-601
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:21130-601-05	1 in 1 CARTON	08/20/2014	
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021996	08/20/2014	

Labeler - Safeway (009137209)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(21130-601)