KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops
Rugby Laboratories

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 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: 1-800-645-2158

Distributed by:
RUGBY® LABORATORIES
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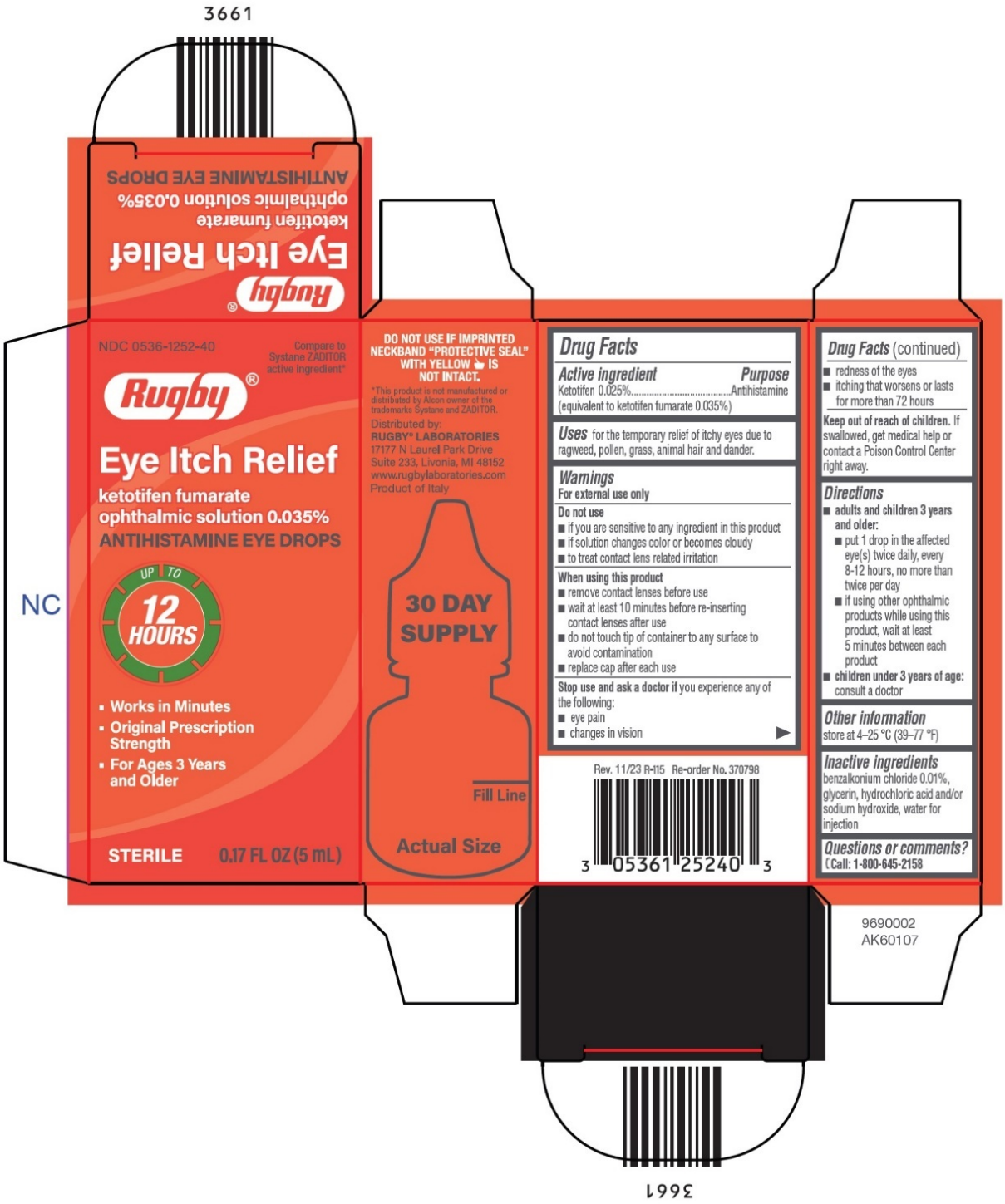
www.rugbylaboratories.com
Product of Italy

9690002

AK60107

Package/Label Principal Display Panel



NDC 0536-1252-40

Rugby®

Compare to
Systane ZADITOR

active ingredient*

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)

KETOTIFEN FUMARATE

ketotifen fumarate solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1252
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:0536-1252-40	1 in 1 CARTON	09/18/2020	
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 authorized generic	NDA021996	09/18/2020	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(0536-1252) , PACK(0536-1252) , LABEL(0536-1252)

Revised: 12/2023 Rugby Laboratories