

EYE ITCH RELIEF- ketotifen fumarate solution/ drops
CVS Pharmacy

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

For external use only

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 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 to 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, Water for Injection. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

Questions or comments?

1 -800-932-5676

Serious side effects associated with use of this product may be reported to this number

Principal Display Panel Text for Container Label:

CVS Health™ Logo

Eye Itch Relief

KETOTIFEN FUMARATE

OPHTHALMIC SOLUTION

0.035%

Antihistamine eye drops

STERILE

5 mL (0.17 FL OZ)

The image shows a rectangular label with rounded corners, outlined in orange. On the left is a barcode with the number 1743 below it and 'XCVZAAL Rev. 06/18' at the bottom. To the right of the barcode is the text: 'Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895 © 2018 CVS/pharmacy CVS.com® 1-800-SHOP CVS Made in Switzerland V-19972'. Below this is the 'CVS Quality Money Back Guarantee' logo. In the center is the 'CVS Health' logo above an orange box containing the text: 'Eye Itch Relief KETOTIFEN FUMARATE OPHTHALMIC SOLUTION 0.035% Antihistamine eye drops STERILE 5 mL (0.17 FL OZ)'. To the right of the orange box is the text: 'ONLY FOR USE IN THE EYE DO NOT USE IF IMPRINTED SEAL ON BOTTLE IS MISSING OR BROKEN Each mL Contains: Active Ingredient: Ketotifen (0.025%) (equivalent to ketotifen fumarate 0.035%). Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Directions: Read detailed consumer information on box before using.' At the bottom right is a barcode with the number '(01)00359779705013' below it.

Principal Display Panel Text for Carton Label:

CVS Health™ Logo Compare to the active ingredient in Zaditor®*

NDC 59779-920-01

Eye Itch GET UP TO

Relief 12

HOURS

OF RELIEF

KETOTIFEN FUMARATE

OPHTHALMIC SOLUTION 0.035%

Antihistamine eye drops

- Works in minutes
- Original prescription strength
- For ages 3 and older
- 60 day supply

TWIN

PACK

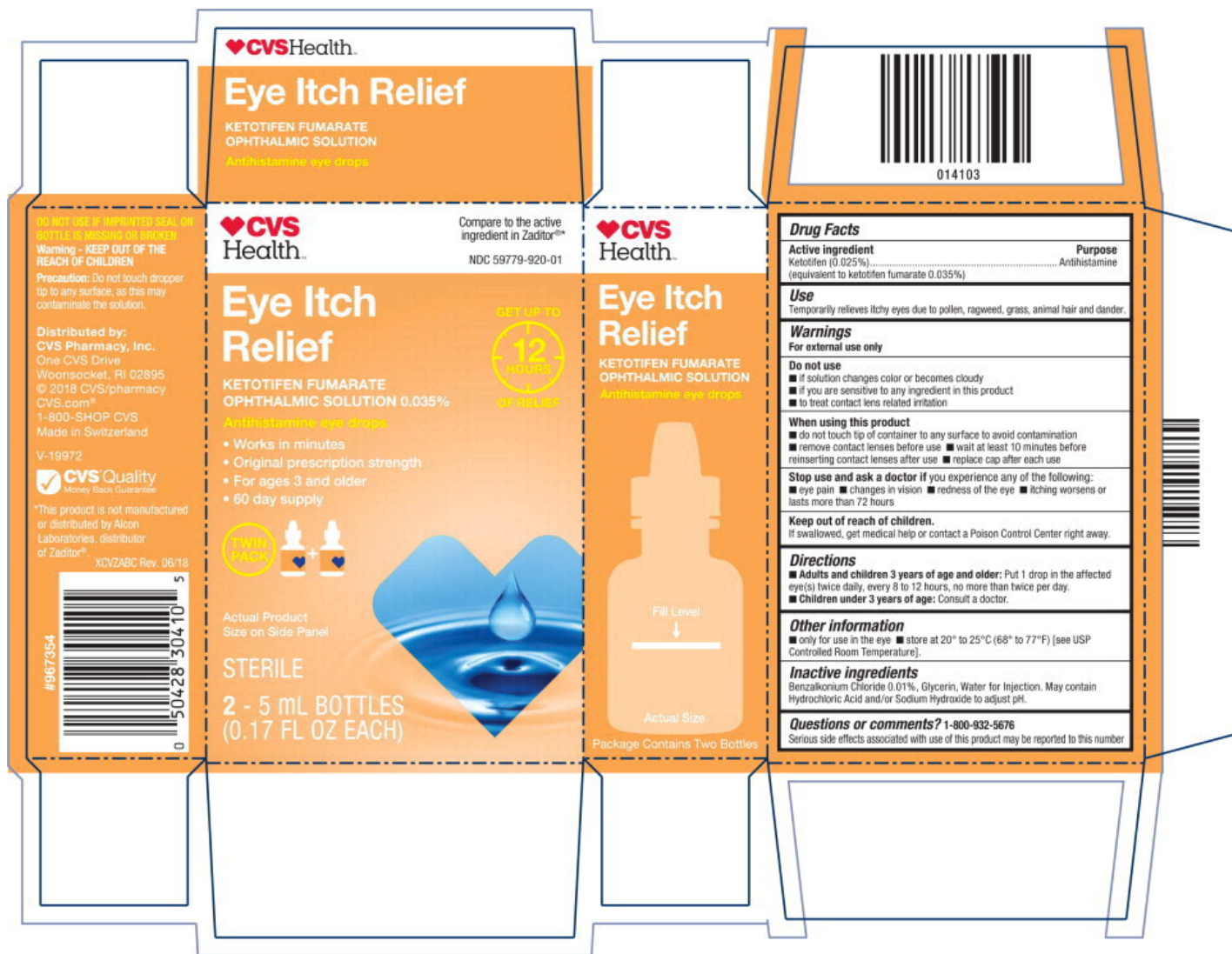
Actual Product

Size on Side Panel

STERILE

2 - 5 mL BOTTLES

(0.17 FL OZ EACH)



EYE ITCH RELIEF

ketotifen fumarate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-920
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ketotifen fumarate (UNII: HBD503WORO) (Ketotifen - UNII:X49220T18G)	Ketotifen	0.35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
benzalkonium chloride (UNII: F5UM2KM3W7)	
glycerin (UNII: PDC6A3C00X)	
water (UNII: 059QF0K00R)	

hydrochloric acid (UNII: QTT17582CB)

sodium hydroxide (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-920-01	2 in 1 CARTON	02/07/2014	
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	02/07/2014	

Labeler - CVS Pharmacy (062312574)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(59779-920) , ANALYSIS(59779-920) , STERILIZE(59779-920) , PACK(59779-920) , LABEL(59779-920)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	MANUFACTURE(59779-920)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	LABEL(59779-920) , PACK(59779-920)

Revised: 2/2022

CVS Pharmacy