CHILDRENS ALLERGY RELIEF - cetirizine hydrochloride solution Fred's, Inc.

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

Cetirizine Hydrochloride USP 5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have

liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are

taking tranquilizers or sedatives.

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery.

Stop use and ask a doctor if

an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding

- If breast-feeding: not recommended
- If pregnant: ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- use only with enclosed dosing cup
- mL=milliliter

adults and children 6 years and over	1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL)
	once daily depending upon severity of symptoms;
	do not take more than 2 teaspoonfuls (10 mL) in 24
	hours.
adults 65 years and over	1 teaspoonful (5 mL) once daily; do not take more
	than 1 teaspoonful (5 mL) in 24 hours.
children 2 to under 6 years of age	1/2 teaspoonful (2.5 mL) once daily. If needed, dose
	can be increased to a maximum of 1 teaspoonful (5
	mL) once daily or 1/2 teaspoonful (2.5 mL) every 12
	hours. Do not give more than 1 teaspoonful (5 mL)
	in 24 hours.
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

store between 20° to 25° C (68° to 77°F)

Inactive ingredients

banana flavor, glacial acetic acid, glycerin, grape flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, sucrose

Questions?

call **1-855-274-4122**

Distributed by: Fred's, Inc. 4300 NEW GETWELL RD, MEMPHIS, TN 38118 www.fredsinc.com

fred's Promise Not Happy With This Product? Just Bring It Back For a Refund!

PACKAGE LABEL- PRINCIPAL DISPLAY PANEL 4 FL OZ (120 mL Bottle)

NDC 55315-354-31

fred*s

 $KIDS_{\mathbb{R}}$ 2 yrs & older

Children's Allergy Relief

Indoor & Outdoor Allergies

Cetirizine Hydrochloride Oral Solution, USP 1mg/mL Antihis tamine Grape Flavored Syrup

24 Hour Relief of:

Sneezing Runny Nose Itchy, Watery Eyes Itchy Nose or Throat

Dosing Cup Included

4 FL OZ (120 mL) Compare to *Children's ZYRTEC®



3002000114

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives. When using this product
drowsiness may occur

- avoid alcoholic drinks
 alcohol, sedatives, and tranquilizers may increase
- drowsiness

 be careful when driving a motor vehicle or operating
- machinery.

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

In product occurs, seek intended help right away. If pregnant or breast-feeding not recommende I for presst-feeding not recommende I for presst-feeding not recommende I for presstor ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions ■ use only with enclosed dosing cup ■ mL=millilite		
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and over | not take more than 1 teaspoormu (
5 mL) in 24 hours.

children 2 to | 1/2 teaspoonful (2.5 mL) once daily. If |
needed, dose can be increased to a |
age | maximum of 1 teaspoonful (3.5 mL) once daily or 1/2 teaspoonful (5.5 mL) one daily or 1/2 teaspoonful (5.5 mL) one daily or 1/2 teaspoonful (5.5 mL) one to the needed to the control of teaspoonful (5.5 mL) one of the needed to the control of teaspoonful (5.5 mL) in 2.4 hours.

children under ask a doctor 2 years of age consumers with liver or kidney disease

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fred's Promise



Children's

Allergies

Antihistamine

Sneezing

or Throat

Dosing Cup

4 FL OZ

(120 mL)

Runny Nose

24 Hour Relief of:

Itchy, Watery Eyes Itchy Nose

Indoor & Outdoor

Cetirizine Hydrochloride

Grape Flavored Syrup

Oral Solution, USP 1 mg/mL

NDC 55315-354-31

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NDC 55315-354-31

2 yrs &older

Children's

Indoor & Outdoor **Allergies**

Cetirizine Hydrochloride Oral Solution, USP 1 mg/mL **Antihistamine**

Grape Flavored Syrup

24 Hour Relief of: Sneezing **Runny Nose** Itchy, Watery Eyes Itchy Nose or Throat Dosing Cup

4 FL OZ (120 mL)



freds

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Indoor & Outdoor Allergies

Dosing cup should be washed and left to air dry after each use. Do not use if carton is opened, or if cap safety seal is broken

Durint deer carron is opened, or it cap saley seals stoken or messing. See bottom panel for expiration date.

"This product is not manufactured or distributed by McNeil Consumer Heathcare, distributor of Children's ZYRTEC® Allergy Syrup. Children's ZYRTEC® Allergy Syrup is a registered trademark of UGB Pharma, S.A. Corporation Belgium

TS/DRUGS/19/1993

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Active ingredient (in each 5 mL teaspoonful) Cetirizine Hydrochloride USP 5 mg..... Purpose

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runny nose sneezing itchy, watery eyes itching of the nose or throat

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CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information

Product Type HUMAN OTC DRUG NDC:55315-354 Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDRO CHLO RIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII: YO7261ME24)	CETIRIZINE HYDROCHLORIDE	1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8 IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM ACETATE (UNII: 4550 K0 SC9 B)	
SUCROSE (UNII: C151H8 M554)	

Product Characteristics		
Color	YELLOW (Colorless to Pale Yellow)	Score
Shape		Size
Flavor	BANANA, GRAPE	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55315-354- 31	1 in 1 CARTON	0 1/31/20 15	
1	120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090750	0 1/3 1/2 0 15	

Labeler - Fred's, Inc. (005866116)

Registrant - Aurohealth LLC (078728447)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aurobindo Pharma Limited		9 18 9 17 6 4 2	MANUFACTURE(55315-354)	

Revised: 12/2020 Fred's, Inc.