

CHILDRENS ALLERGY RELIEF - cetirizine hydrochloride solution
Aurohealth LLC

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
- find right dose on chart below
- 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	½ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or ½ 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)
- **Do not use if carton is opened, or if cap safety seal is broken or missing**

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**

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's ZYRTEC[®] Allergy Syrup. Children's ZYRTEC[®] Allergy Syrup is a registered trademark of UCB Pharma, S.A. Corporation Belgium

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 or missing.

Distributed by: AUROHEALTH LLC,
2572 Brunswick Pike,
Lawrenceville, NJ 08648
a division of Aurobindo Pharma USA, Inc.
6 Wheeling Road, Dayton NJ 08810

Made in INDIA

Code: TS/DRUGS/19/1993

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 mg/mL (120 mL Bottle)

AUROHEALTH

NDC 58602-422-12

*Compare to active ingredient in Children's ZYRTEC[®] Allergy Syrup

Children's Allergy Relief

Cetirizine Hydrochloride Oral Solution USP 1 mg/mL

antihistamine

Indoor & Outdoor Allergies

24 hour relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy nose or throat

Dye Free Grape Syrup
4 fl oz (120 mL)

2 yrs. & older

AUROHEALTH

NDC 58602-422-12
 *Compare to active ingredient in Children's ZYRTEC® Allergy Syrup

Children's Allergy Relief
Cetirizine Hydrochloride
Oral Solution USP 1 mg/mL
antihistamine
 Indoor & Outdoor Allergies
24 hour relief of:
 • Sneezing • Itchy, watery eyes
 • Runny nose • Itchy nose or throat
4 fl oz (120 mL)



Dye-Free Grape Syrup
 2 yrs. & older

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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

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3001000406

LOT EXP

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 mg/mL Carton (120 mL)

AUROHEALTH

NDC 58602-422-12

*Compare to active ingredient in Children's ZYRTEC® Allergy Syrup

Children's Allergy Relief
Cetirizine Hydrochloride Oral Solution USP
1 mg/mL

antihistamine

Indoor & Outdoor Allergies

24 hour Relief of

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy nose or throat

2 yrs. & older

Dye-Free Grape Syrup

4 fl oz (120 mL)

Dosing Cup Included



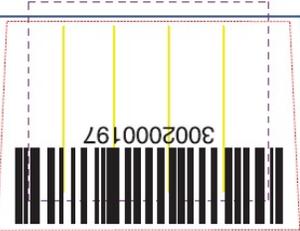
Children's Allergy Relief
 Cetirizine Hydrochloride
 Oral Solution USP
 1 mg/mL

antihistamine

Indoor & Outdoor Allergies



3002000197



Children's Allergy Relief
 Cetirizine Hydrochloride
 Oral Solution USP
 1 mg/mL

antihistamine

Indoor & Outdoor Allergies

24 hour relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy nose or throat



4 fl oz (120 mL) Dosing Cup Included



LOT
EXP



Children's Allergy Relief
 Cetirizine Hydrochloride
 Oral Solution USP
 1 mg/mL

antihistamine

Indoor & Outdoor Allergies

24 hour relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy nose or throat



4 fl oz (120 mL) Dosing Cup Included

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 Cetirizine Hydrochloride USP 5 mg.....Antihistamine

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 ■ if breast-feeding, not recommended
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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



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Drug Facts (continued)

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CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-422
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SUCROSE (UNII: C151H8M554)	

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:58602-422-12	1 in 1 CARTON	02/02/2010	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-422-20	1 in 1 CARTON	02/02/2010	
2		240 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
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ANDA	ANDA090750	02/02/2010	
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Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-422) , MANUFACTURE(58602-422)

Revised: 11/2022

Aurohealth LLC