

CHILDRENS ALLERGY RELIEF - cetirizine hydrochloride solution
Aurohealth LLC

Drug Facts

Active ingredient (in each 5 mL)

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	5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours.
adults 65 years and over	5 mL once daily; do not take more than 5 mL in 24 hours.
children 2 to under 6 years of age	2.5 mL once daily. If needed, dose can be increased to a maximum of 5 mL once daily or 2.5 mL every 12 hours. Do not give more than 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.**
- see bottom panel for lot number and expiration date

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**

(Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road

East Windsor, NJ 08520

Made in India

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

AUROHEALTH

NDC 58602-422-12

Children's

Cetirizine Hydrochloride

Oral Solution USP 1 mg/mL

antihistamine

24 Hour

relief of

Itchy, Watery

Eyes

Sneezing

Itchy Throat

or Nose

Runny Nose

Dye-Free

Alcohol-Free

ALLERGY

Indoor &

Outdoor

Allergies

2 yrs &

older

Grape Flavor

4 fl oz (120 mL)

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Children's
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24 Hour relief of
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 Indoor & Outdoor Allergies
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4 fl oz (120 mL)

Active ingredient (in each 5 mL)
 Cetirizine hydrochloride USP 5 mg.....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: 5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours. ■ adults 65 years and over: 5 mL once daily; do not take more than 5 mL in 24 hours. ■ children 2 to under 6 years of age: 2.5 mL once daily. If needed, dose can be increased to a maximum of 5 mL once daily or 2.5 mL every 12 hours.

Purpose
 Do not give more than 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 the cap safety seal is broken or missing.**
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Dosing cup should be washed and left to air dry after each use.

Distributed by:
AUROHEALTH LLC
 279 Princeton-Hightstown Road
 East Windsor, NJ 08520

Made in India

P1436145

* Unvarnished Zone (dotted line not for printing) 46 x 15 mm

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

AUROHEALTH

NDC 58602-422-12

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

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

ALLERGY

Indoor & Outdoor Allergies

2 yrs & older

24 Hour relief of

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

Dye-Free Alcohol-Free

Grape Flavor
4 fl oz (120 mL)

Dosing cup
included

Glue

Drug Facts

Active ingredient (in each 5 mL)	Purpose
Cetirizine hydrochloride USP 5 mg...Antihistamine	

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Drug Facts (continued)

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*This product is not manufactured or distributed by Johnson and Johnson Consumer Inc., Monell Consumer Healthcare Division, distributor of Children's Zyrtec®

AUROHEALTH

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

ALLERGY

AUROHEALTH

Children's
**Cetirizine Hydrochloride
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1 mg/mL

antihistamine

ALLERGY



Indoor &
Outdoor
Allergies

2 yrs &
older



Grape Flavor

4 fl oz (120 mL)



Dosing cup
included

AUROHEALTH

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

antihistamine

ALLERGY



Grape Flavor

4 fl oz (120 mL)



Dosing cup
included



P1058993

Unvarnished Zone
(dotted line not for printing)
48 x 19 mm

*Lot: XXXXXXXX
Exp.: YYYY-MMM
Prefix, Variables of Lot, Exp and
Neutral code shall be
printed online during packing.

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		
	NDC:58602			

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		
3	NDC:58602-422-17	480 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	02/02/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090750	02/02/2010	

Labeler - Aurohealth LLC (078728447)

Establishment

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

Revised: 12/2025

Aurohealth LLC