

CHILDRENS CETIRIZINE HYDROCHLORIDE ALLERGY - 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	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

cherry mint flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate trihydrate, sucrose

Questions?

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

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.

Manufactured for:

AUROHEALTH LLC,
2572 Brunswick Pike,
Lawrenceville, NJ 08648

Manufactured by:

Aurobindo Pharma Limited
Hyderabad-500 090, India

M.L.No.: 19/HD/AP/95/F/R

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

AUROHEALTH

NDC 58602-028-24

Children's

Cetirizine Hydrochloride

Oral Solution USP

1 mg/mL

antihistamine *ALLERGY*

Indoor & Outdoor Allergies

24 hour

Relief of

- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**
- **Itchy Throat or Nose**

2 yrs.& older

Cherry Flavor

Dye-Free

4 fl oz (120 mL)

Dosing cup should be washed and left to air dry after each use.
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AUROHEALTH
NDC 58602-028-24

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
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4 fl oz (120 mL) Dye-Free Cherry Flavor

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3001000062

Drug Facts
Active ingredient (in each 5 mL) Purpose
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.**

Lift Here

Labeling Format Information:	
Font type :	Helvetica Condensed
Barline :	2.5 pt
Hairline :	NA
Drug facts :	9 pt
Drug facts (continued):	8 pt
Header :	7 pt
Subheader :	6 pt
Leading :	0.5 pt
Body text :	6 pt
Bullets :	5 pt

 Pattern denotes LOT/EXP area
- NO VARNISH - NO COPY
- NO BACKGROUND COLOR

Top ply (Back)

Drug Facts (continued)
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

Drug Facts (continued)
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

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

AUROHEALTH

NDC 58602-028-24

Children's

Cetirizine Hydrochloride

Oral Solution USP

1 mg/mL

antihistamine

ALLERGY

Indoor & Outdoor Allergies

24 hour

Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

2 yrs. & older
Cherry Flavor
Dye-Free
4 fl oz (120 mL) Dosing Cup Included

No Coating Area
300200049

No Coating Area

Glue

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: <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ Itchy, watery eyes ■ Itching of the nose or throat 	
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AUROHEALTH

No Coating Area
300200049

No Coating Area

No Coating Area
300200049

No Coating Area

LOT

EXP

N.C. Area

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CHILDRENS CETIRIZINE HYDROCHLORIDE ALLERGY
 cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-028
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	CHERRY (Cherry Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-028-24	1 in 1 CARTON	06/24/2015	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-028-20	1 in 1 CARTON	06/24/2015	
2		240 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
3	NDC:58602-028-26	480 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	06/24/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090750	06/24/2015	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-028) , MANUFACTURE(58602-028)

Revised: 11/2022

Aurohealth LLC