

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	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

cherry mint flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate trihydrate, 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 58602-028-24

Children's

Cetirizine Hydrochloride

Oral Solution USP 1 mg/mL

antihistamine

24 Hour

relief of

Sneezing

Runny Nose

Itchy, Watery

Eyes

Itchy Throat

or Nose

Dye-Free

Alcohol-Free

ALLERGY

Indoor &

Outdoor

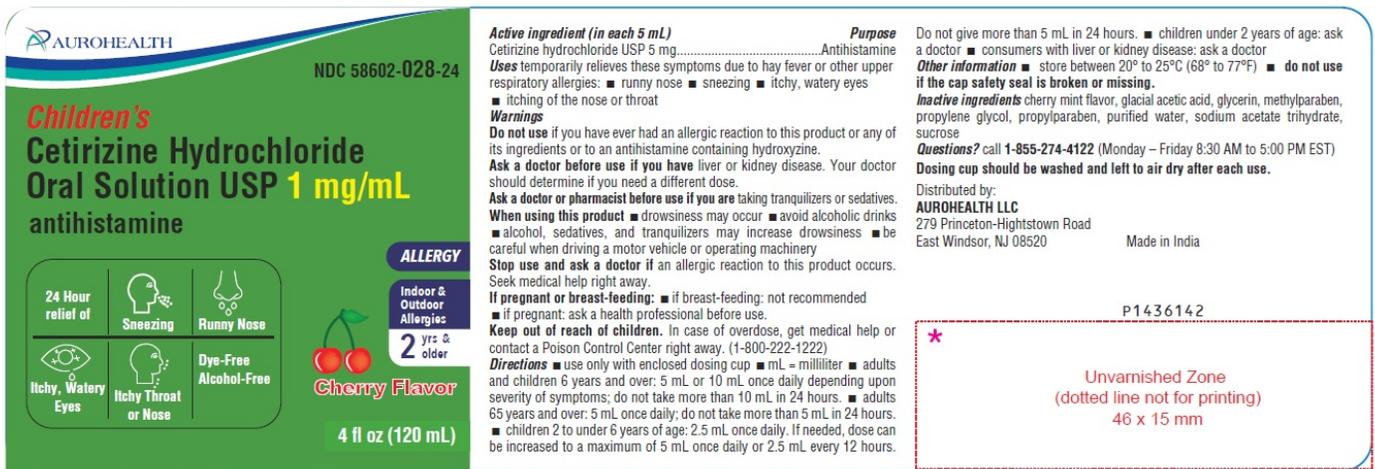
Allergies

2 yrs &

older

Cherry Flavor

4 fl oz (120 mL)



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

AUROHEALTH

NDC 58602-028-24

***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

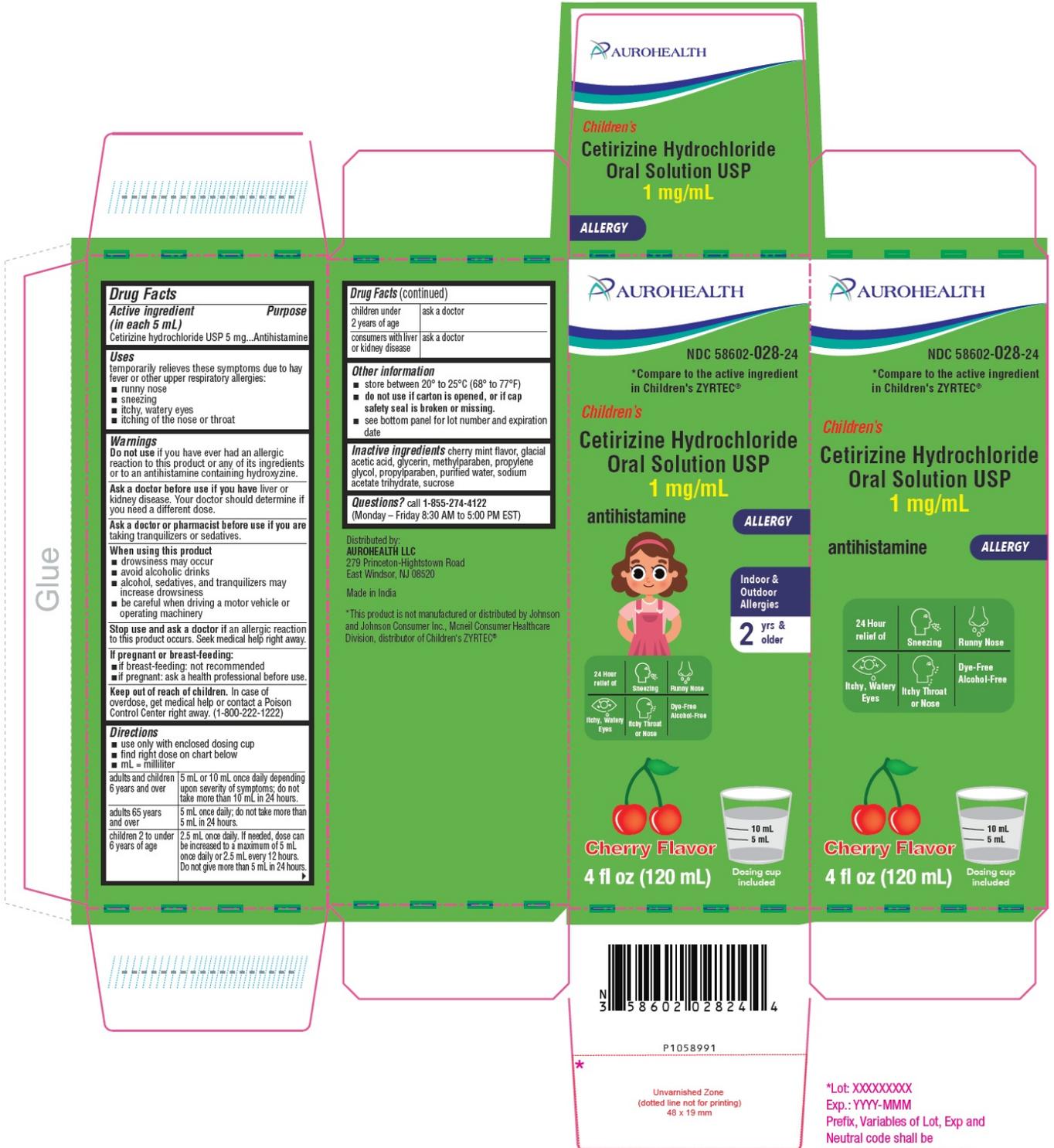
**Itchy, Watery
Eyes**

**Itchy Throat
or Nose**

**Dye-Free
Alcohol-Free**

Cherry Flavor 4 fl oz (120 mL)

Dosing cup
included



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Cetirizine hydrochloride USP 5 mg...Antihistamine	

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

Made in India

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

AUROHEALTH

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

ALLERGY

AUROHEALTH

NDC 58602-028-24

*Compare to the 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

Cherry Flavor
4 fl oz (120 mL)

Dosing cup included

AUROHEALTH

NDC 58602-028-24

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P1058991

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

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

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: 12/2025

Aurohealth LLC