

CHILDRENS CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
Sun Pharmaceutical Industries, Inc.

Children's Cetirizine Hydrochloride Oral Solution
Sugar Free -Paraben Free Grape

Drug Facts

Active ingredient (in each 5 mL)

Cetirizine HCl 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 older	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

- **each 5mL contains:**sodium 4 mg
- **do not use if carton is opened or if imprinted safety seal is broken or missing**
- see bottom panel for lot number and expiration date
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

artificial grape flavor, glacial acetic acid, glycerin, propylene glycol, purified water, sodium acetate anhydrous, sodium benzoate, sucralose

Questions?

Call **1-866-923-4914**

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

120 mL Carton

Compare to the

active ingredient
in Children's Zyrtec®*

NDC 51672-2147-8



**NO VARNISH
ON THIS FLAP**

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Drug Facts	
Active ingredient (in each 5 mL) Cetirizine HCl 5 mg.....Antihistamine	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)	

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**NO COPY ON THIS FLAP
FOR LOT # AND EXPIRY
DATE PRINT**



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ON THIS FLAP**

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Compare to the active ingredient in Children's Zyrtec®*

NDC 51672-2147-8

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

*Antihistamine
Indoor & Outdoor Allergies*

Compare to the active ingredient in Children's Zyrtec®*

NDC 51672-2147-8

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

*Antihistamine
Indoor & Outdoor Allergies*

Sugar Free • Paraben Free

24 Hour Relief of:

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

2 Yrs. & older



Grape Flavor

4 FL OZ
(120 mL)

Dosing Cup Included

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

*Antihistamine
Indoor & Outdoor Allergies*

- Sugar Free • Paraben Free
- Alcohol Free • Dye Free

Dosing Cup Included



Grape Flavor

Dosing cup should be washed and left to air dry after each use.

*All trademarks are property of their respective owners. This product is not affiliated with the makers of Zyrtec®.

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.**
Denville, NJ 07832
TARO is a registered trademark of
Taro Pharmaceuticals U.S.A., Inc. Made in Canada

CHILDRENS CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2147
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM ACETATE ANHYDROUS (UNII: NVG71ZZ7P0)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ACETIC ACID (UNII: Q40Q9N063P)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2147-8	1 in 1 CARTON	03/20/2025	

1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product	
2	NDC:51672-2147-1	1 in 1 CARTON	03/20/2025
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090182	03/20/2025	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(51672-2147)

Revised: 7/2025

Sun Pharmaceutical Industries, Inc.