

CHILDRENS CETIRIZINE HYDROCHLORIDE SUGAR FREE GRAPE- cetirizine hydrochloride solution

Taro Pharmaceuticals U.S.A., Inc.

**Children's Cetirizine Hydrochloride Oral Solution
Sugar 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
- itchy, watery eyes
- sneezing
- 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

- **do not use if carton is opened, or if imprinted safety seal is broken or missing**
- see bottom panel for expiration date
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

artificial grape flavor, glacial acetic acid, glycerin, methylparaben, natural and artificial banana flavor, propylene glycol, propylparaben, purified water, sodium acetate (anhydrous), sucralose

Questions?

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

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

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

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

NDC 51672-2102-8

Children's
Cetirizine
Hydrochloride
Oral Solution
1 mg/mL

ALLERGY
Antihistamine

Indoor & Outdoor Allergies

SUGAR FREE

24
Hour
Relief of:

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

2 Yrs. & older

Grape Flavor

Dosing Cup Included

4 FL OZ
(120 mL)

NO VARNISH
ON THIS FLAP

SEALED WITH PRINTED NECKBAND

Drug Facts

Active Ingredient Purpose (In each 5 mL)
Cetirizine HCl 5 mg.....Antihistamine

Uses
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
• runny nose
• sneezing
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Warnings
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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)

Drug Facts (continued)

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.
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adults 65 years and over	5 mL once daily; do not take more than 5 mL in 24 hours.
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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.
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children under 2 years of age	ask a doctor
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consumers with liver or kidney disease	ask a doctor
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Other information

- 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°O (68° to 77°F)

Inactive ingredients

artificial grape flavor, glacial acetic acid, glycerin, methylparaben, natural and artificial banana flavor, propylene glycol, propylparaben, purified water, sodium acetate (anhydrous), sucralose

Questions?

Call 1-866-923-4914

NDC 51672-2102-8

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

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

Antihistamine
Indoor & Outdoor Allergies

NDC 51672-2102-8

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

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

Antihistamine
Indoor & Outdoor Allergies

SUGAR FREE

24 Hour Relief of:
• Sneezing
• Runny Nose
• Itchy, Watery Eyes
• Itchy Throat or Nose

2 Yrs. & older



Grape Flavor

Dosing Cup Included

4 FL OZ (120 mL)

Children's Cetirizine Hydrochloride Oral Solution
1 mg/mL ALLERGY
Antihistamine
Indoor & Outdoor Allergies

• Dye Free • Sugar Free



Grape Flavor

Dosing Cup Included

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

* This product is not manufactured or distributed by UCB Pharma, S.A. CORPORATION BELGIUM, owner of the registered trademark Children's Zyrtec®.

Distributed by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532
TARO is a registered trademark of Taro Pharmaceuticals U.S.A., Inc. Made in Canada

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ON THIS FLAP

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FOR LOT # AND EXPIRY
DATE PRINT

T181C



CHILDRENS CETIRIZINE HYDROCHLORIDE SUGAR FREE GRAPE
cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetirizine Hydrochloride (UNII: 640047KTOA) (Cetirizine - UNII:YO7261ME24)	Cetirizine Hydrochloride	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
acetic acid (UNII: Q40Q9N063P)	
glycerin (UNII: PDC6A3C00X)	
methylparaben (UNII: A2I8C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sodium acetate anhydrous (UNII: NVG71ZZ7P0)	
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE, BANANA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2102-4	1 in 1 CARTON	09/08/2011	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2102-8	1 in 1 CARTON	09/08/2011	
2		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51672-2102-1	1 in 1 CARTON	09/08/2011	
3		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:51672-2102-2	2 in 1 CARTON	09/08/2011	
4		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:51672-2102-7	2 in 1 CARTON	09/08/2011	
5		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
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ANDA	ANDA090182	09/08/2011	
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Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries, Ltd.		600072078	MANUFACTURE(51672-2102)

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2102)

Revised: 4/2021

Taro Pharmaceuticals U.S.A., Inc.