CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
Taro Pharmaceuticals U.S.A., Inc.

Children's Cetirizine Hydrochloride Oral Solution

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 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

- **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

bubble gum artificial flavor, glacial acetic acid, glycerin, methylparaben, 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 51672-2106-8

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

Bubble Gum
Flavor

Dosing Cup Included

4 FL OZ
(120 mL)

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2106
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 anhydrous (UNII: NVG71ZZ7P0)	
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	YELLOW (colorless to slightly yellow)	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2106-8	1 in 1 CARTON		
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2106-1	1 in 1 CARTON		
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51672-2106-4	1 in 1 CARTON		
3		60 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	ANDA201546	05/20/2011	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries, Ltd.		600072078	MANUFACTURE(51672-2106)