

**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 LABEL	Item Code (Source)	NDC:51672-2106
Route of Administration	ORAL	DEA Schedule	

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Cetirizine Hydrochloride (Cetirizine)	Cetirizine Hydrochloride	1 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
acetic acid	
glycerin	
methylparaben	
propylene glycol	
propylparaben	
water	
sodium acetate anhydrous	
sucralose	

**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; Combination Product Type = C112160		
2	NDC:51672-2106-1	1 in 1 CARTON		
2		240 mL in 1 BOTTLE; Combination Product Type = C112160		
3	NDC:51672-2106-4	1 in 1 CARTON		
3		60 mL in 1 BOTTLE; Combination Product Type = C112160		

**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)

