CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
Taro Pharmaceutical Industries, Ltd.

Children's
Cetirizine
Hydrochloride
Oral Solution

Active ingredient (in each 5 mL teaspoonful)

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 breastfeeding: 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
- adults and children 6 years and over: 1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily

depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
- adults 65 years and older: 1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.
- children 2 to under 6 years of age: 1/2 teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or 1/2 teaspoonful (2.5 mL) every 12 hours. Do not give more than 1 teaspoonful (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)

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**

Dosing cup should be washed and left to air dry after each use. Do not use if carton is opened or if imprinted safety seal is torn or missing.

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

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 51672-2106-8

Children's
Cetirizine
Hydrochloride
Oral Solution

1 mg/mL
Antihistamine

ALLERGY
Indoor & Outdoor Allergies

2 Yrs.
& older

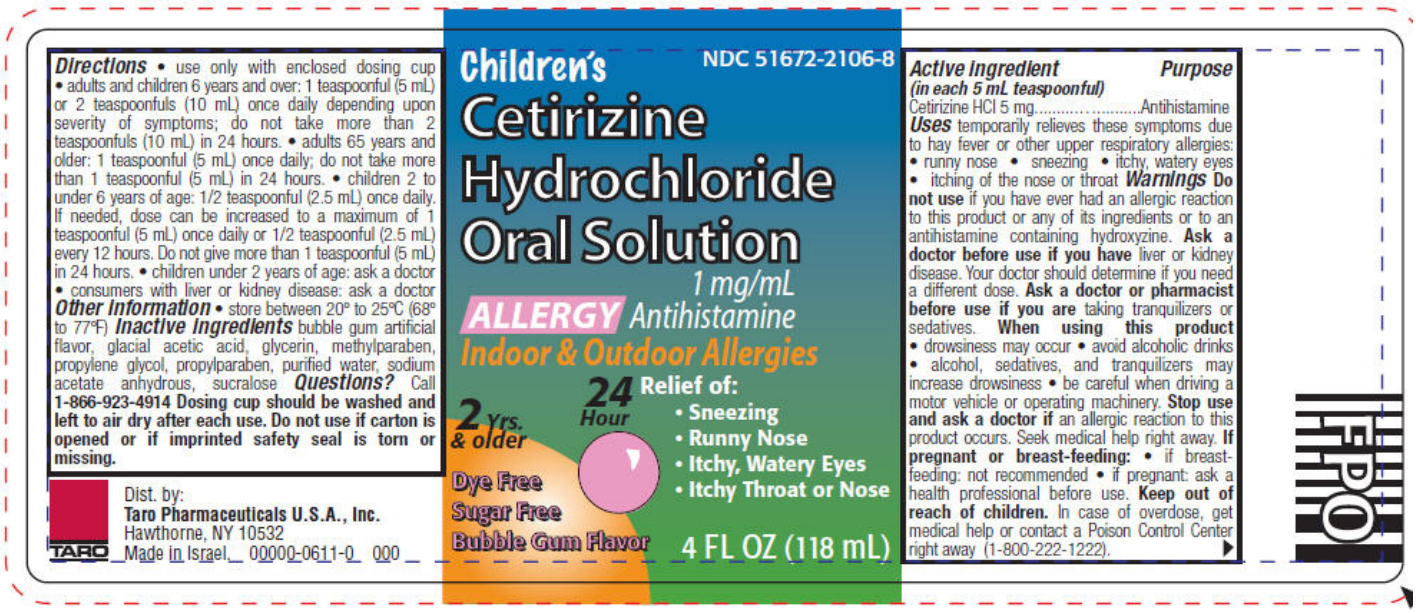
Dye Free
Sugar Free
Bubble Gum Flavor

24
Hour

Relief of:
- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**

- **Itchy Throat or Nose**

4 FL OZ (118 mL)



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52549-2106
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:52549-2106-8	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		
2	NDC:52549-2106-1	1 in 1 CARTON		
2		237 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201546	05/20/2011	

Labeler - Taro Pharmaceutical Industries, Ltd. (600072078)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries, Ltd.		600072078	MANUFACTURE

Revised: 7/2011 Taro Pharmaceutical Industries, Ltd.