CHILDRENS CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
Chain Drug Consortium, LLC (Premier Value)

CHILDREN'S
CETIRIZINE
HYDROCHLORIDE
ORAL SOLUTION
1 mg/1 mL
Antihistamine

Drug Facts

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
- 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.

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

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

Questions?

Call 1-866-923-4914

Distributed by: **Chain Drug Consortium, LLC**
2300 NW Corporate BLVD., Suite 115
Boca Raton, FL 33431
Made in Israel

PRINCIPAL DISPLAY PANEL - 120 mL bottle carton

NDC 68016-023-43

Ages
two years
and older

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

Premier
Value®

CHILDREN'S

CETIRIZINE
HYDROCHLORIDE
ORAL SOLUTION
1 mg/1 mL
Antihistamine

Grape Flavored Syrup

24 hour Allergy Relief of:
Sneezing; Runny Nose;
Itchy,Watery Eyes;
Itchy Throat or Nose

Indoor & Outdoor Allergies

Dosing Cup
Included

PV
PREMIER VALUE GUARANTEE

4 FL OZ (120 mL)

CHILDRENS CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-023
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetirizine Hydrochloride (UNII: 64O047KTOA) (Cetirizine - UNII:YO7261ME24)	Cetirizine Hydrochloride	5 mg in 5 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)	
sucrose (UNII: C151H8M554)	

Product Characteristics

Color	YELLOW (colorless to slightly yellow)	**Score**	
Shape		**Size**	
Flavor	GRAPE, BANANA	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-023-43	1 in 1 CARTON	04/22/2008	
1		120 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	04/22/2008	

Labeler - Chain Drug Consortium, LLC (Premier Value) (101668460)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	ANALYSIS(68016-023) , MANUFACTURE(68016-023)

Revised: 1/2019 Chain Drug Consortium, LLC (Premier Value)