PREMIER VALUE CHILDRENS CETIRIZINE- cetirizine hydrochloride solution Chain Drug Constortium

Premier Value Children's Cetirizine

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 (1-800-222-1222).

Directions

• use only with enclosed dosing cup

adults and children 6 years and over	once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
adults 65 years and	1 teaspoonful (5 mL) once daily; do not take more
older	than 1 teaspoonful (5 mL) in 24 hours.
children 2 to under 6 years of age	½ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or ½ 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), sucralose

Questions?

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

DISTRIBUTED BY CHAIN DRUG CONSORTIUM 3301 NW BOCA RATON BLVD, SUITE 101 BOCA RATON, FL 33431

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 68016-165-00

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S ZYRTEC®*

Premier Value

Ages two years and older

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

SUGAR FREE GRAPE flavor

24 hour Allergy

Relief of: Sneezing;

Runny Nose; Itchy, Watery Eyes;

Itchy Throat or Nose

INDOOR & OUTDOOR ALLERGIES

Dosing Cup Included

INDEPENDENTLY TESTED

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SATISFACTION GUARANTEED

4 FL OZ (120 mL)



999 20325-0512-0







Ages two years and older

Cetirizine Hvdrochloride Oral Solution 1 mg/mL

Antihistamine

- Alcohol Free
 Dye Free
- Gluten Free

Dosing up should be washed and left to air dry after each use. Do not use if carton is opened, or if in printed safety seal is broken or nissing. See bottom panel for expiration date.

"This product is not manufactured or distributed by OCB Pharma, S.A., CORPORA TION BELGIUM, owner of the registered trademark Children's Zyrtec".



Drug Facts

Active ingredient (in each 5 mL teaspoonful) Catrizina HCI 5 mg.....

Purpose .Antihistamine

Uses temporarily relieves these symptoms due to hay lever or Uses temporary energias:
other upper respiratory allergies:
other upper respiratory allergies:
tothy, watery eyes
otherwise
itching of the nose or throat

Drug Facts (continued)

Warnings Do not use if you have ever had an alergic reaction to this product or any of its ingredients or to an ant histamine containing hydroxycine.

Ask a doctor before use if you have liver or kichey disease. Your doctor should determine if you need a different dose. Ask a doctor or pharmacist before use if you are taking tranquitizers or sadatives.

When using this product

- ortowarises may occur avoid a locholic dirks alcohol, sedatives, and tranqu lizers may increase drowsiness be careful when driving a motorvehide or operating mach inery 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 see mmended

 if pagrant aska heat hip 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 1 teespoonful (5 mL) or 2 teespoonfuls (10 mL) once daily depending upon severity of symptoms, do not take more than 2 teespoonfuls (10 mL) in 24 hours. children 2 to under 6 years of age

tespoonful (5 mL) once daily do not take more than 1 tespoonful (5 mL) once daily. If needed, dose can be increased to a maximum of 1 tespoonful (5 mL) once daily or yet tespoonful (5 mL) once daily or yet tespoonful (5 mL) once daily or yet give more than 1 téaspoonful (5 mL) in 24 hours. aska docto

children under 2 years of age consumers with liver or kidney disease

Other information

store between 20° to 25°C (68° to 77°F)

Inactive ingredients artifdal grape taxx, gladal acetic acid, glycarin, mehylparaben, natural and artifidal berana faxx, propylene glycol, propylparaben, putified water, sodium acetate (arthydrous), sucratice

Questions? Call 1-866-923-4914

DISTRIBUTED BY CHAIN DRUG CONSORTIUM 3301 NW BOCA RATON BLVD, SUITE 101 BOCA RATON, FL 33431 MADE IN ISRAEL



PREMIER VALUE CHILDRENS CETIRIZINE

cetirizine hydrochloride solution

Product Information

HUMAN OTC DRUG LABEL NDC:68016-165 Product Type Item Code (Source)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetirizine Hydrochloride (Cetirizine)	Cetirizine Hydrochloride	5 mg in 5 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	GRAPE (sugar free)	Imprint Code	
Contains			

]	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-165-00	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090182	09/08/2011	

Labeler - Chain Drug Constortium (101668460)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(68016-165)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(68016-165)

Revised: 1/2013 Chain Drug Constortium