QUALITY CHOICE CHILDRENS ALLERGY RELIEF- cetirizine hydrochloride solution Chain Drug Marketing Association

Quality Choice_® Children's Allergy Relief

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	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 **1-800-935-2362**

DISTRIBUTED BY QUALITY CHOICE 43157 WEST NINE MILE ROAD NOVI, MI 48376-0995

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

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

QC QUALITY $CHOICE_{\Re}$

NDC 63868-133-04

Children's ALLERGY RELIEF

Cetirizine Hydrochloride Oral Solution 1 mg/mL

Antihis tamine

Indoor & Outdoor Allergies

24 hour relief of sneezing; runny nose; itchy, watery eyes; itchy throat or nose

Dosing cup should be washed and left to air dry after each use

GRAPE FLAVORED SYRUP

2 yrs. & olderDosing Cup Included

4 FL OZ (118 mL)

Children's

Cetirizine Hydrochloride Oral Solution 1 mg/mL Antihistamine

Indoor & Outdoor Allergies

GRAPE FLAVORED SYRUP

969 70843-0810-0



Children's

Cetirizine Hydrochloride **Oral Solution** 1 mg/mL Antihistamine Indoor & Outdoor Allergies

> 24 hour relief of sneezing; runny nose; itchy, watery eyes; itchy throat or nose

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QUALITY

Children's

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Dosing cup should be washed and left to air dry after each use



4 FL OZ (118 mL)

QUALITY

Children's

Cetirizine Hydrochloride Oral Solution 1 mg/mL Antihistamine

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 broken or missing.

See bottom panel for expiration date.

This product is not manufactured or distributed by UCB Pharma, S.A. CORPORATION BELGIUM, owner of the registered trademark Zyrted[®].

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Drug Facts (continued)

Warnings
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Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

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

Other information

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Questions? Call 1-800-935-2362



Purpose

Antihistam ine

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QUALITY CHOICE CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63868-133

ORAL

Active Ingredient/Active Moiety

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ı	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 (UNII: 4550K0SC9B)			
sucrose (UNII: C151H8M554)			

Product Characteristics			
Color	YELLOW (colorless to slightly yellow)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63868-133-04	1 in 1 CARTON			
1		118 mL in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA090182	04/22/2008		

Labeler - Chain Drug Marketing Association (011920774)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(63868-133)