

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

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	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	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 **248-449-9300**

Distributed by C.D.M.A., Inc.

43157 W. Nine Mile
Novi, MI 48376-0995

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

**QC
QUALITY
CHOICE®**

NDC 63868-093-08

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

children's
**Allergy
Relief**

Cetirizine Hydrochloride
Oral Solution, 1 mg/mL
Antihistamine

**Indoor & Outdoor
Allergies**

24 Hour Relief of:

Runny Nose | Sneezing
Itchy, watery eyes
Itchy throat or nose

2 Yrs. & older

**Sugar Free
Grape
Flavor**

Dosing Cup
Included

4 FL OZ (120 mL)

NDC 63868-093-08

children's
Allergy Relief
Cetirizine Hydrochloride
Oral Solution, 1 mg/mL
Antihistamine

Indoor & Outdoor Allergies

674

20378-0712-0

NDC 63868-093-08

children's
Allergy Relief
Cetirizine Hydrochloride
Oral Solution, 1 mg/mL
Antihistamine

Indoor & Outdoor Allergies

24 Hour Relief of:
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2 Yrs. & older
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children's
Allergy Relief
Cetirizine Hydrochloride
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Indoor & Outdoor Allergies

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 Children's Zyrtec.

Drug Facts	Purpose
Active ingredient (in each 5 mL teaspoonful) Cetirizine HCl 5 mg	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

Drug Facts (continued)

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Questions? Call 248-448-9300



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43157 W Nine Mile
Novi, MI 48376-0995
www.qualitychoice.com
Questions: 248-448-9300

Made in Israel



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QUALITY CHOICE CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-093
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	GRAPE, BANANA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-093-08	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 Marketing Association Inc. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries, Ltd.		600072078	MANUFACTURE(63868-093)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(63868-093)