

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

1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once

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

bubble gum artificial flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate anhydrous, sucralose

Questions?

Call **248-449-9300**

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43157 W. Nine Mile
Novi, MI 48376-0995

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

**QC
QUALITY
CHOICE®**

NDC 63868-106-08

**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

Bubble

Gum

Flavor

Dosing Cup Included

4 FL OZ (120 mL)



NDC 63868-106-08

children's

Allergy Relief

Cetirizine Hydrochloride
Oral Solution, 1 mg/mL
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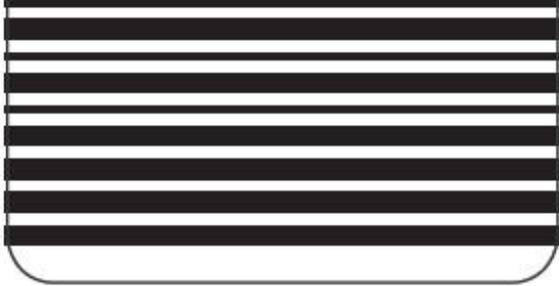
**Sugar Free
Bubble
Gum**



Flavor

Dosing Cup Included

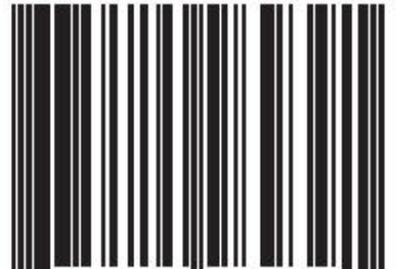
4 FL OZ (120 mL)



Flavor

Dosing Cup Included

4 FL OZ (120 mL)



6 35515 96939 1

989
20473-1212-0

NDC 63868-106-08



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

children's

Allergy Relief

Cetirizine Hydrochloride

Drug Facts (continued)

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Cetirizine Hydrochloride
Oral Solution, 1 mg/mL
Antihistamine

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	
Active ingredient <i>(in each 5 mL teaspoonful)</i>	Purpose
Cetirizine HCl 5 mg.....	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

Read the Drug Facts on the Carton and Carton Right Away (1-800-222-1222).

Directions • use only with enclosed dosing cup

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www.qualitychoice.com
 Questions: 248-449-9300

Made in Israel

QUALITY CHOICE CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-106
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
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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 (Sugar Free)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-106-08	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	ANDA201546	05/20/2011	

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(63868-106)