## CHILDRENS 24 HOUR ALLERGY- cetirizine hydrochloride solution Meijer Distribution Inc

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Children's 24 Hour Allergy

**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	1 teaspoonful (5 mL) once daily; do not take more than
older	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

- do not use if carton is opened, or if imprinted safety seal is broken or missing.
- see bottom panel for expiration date
- 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

DIST. BY MEIJER DISTRIBUTION, INC. GRAND RAPIDS, MI 49544

## PRINCIPAL DISPLAY PANEL - 240 mL Bottle Carton

NDC 41250-102-01

Compare to
Children's
Zyrtec®
active ingredient\*

meijerтм

**Sugar Free** 

2 Years and Older

Children's 24 Hour Allergy

Cetirizine Hydrochloride Oral Solution 1 mg/mL

## **Antihis tamine**

Grape Flavor DYE-FREE

Indoor & Outdoor Allergies 24 Hour Relief of:

Sneezing / Runny Nose Itchy, Watery Eyes Itchy Throat or Nose

Dosing Cup Included

8 FL OZ (240 mL)



NDC 41250-102-01

# meijer

Compare to Children's Zyrtec® active ingredient\*

**Sugar Free** 

2 Years and Older

## Children's 24 Hour Allergy

Cetirizine Hydrochloride Oral Solution 1 mg/mL **Antihistamine** 

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Indoor & Outdoor Allergies

24 Hour Relief of:

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NDC 41250-102-01

## meijer

Compare to Children's Zyrtec® active ingredient\*

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## Children's 24 Hour Allergy

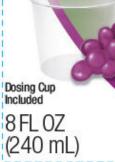
Cetirizine Hydrochloride Oral Solution 1 mg/mL **Antihistamine** 

# Grape Flavor Dye-Free

Indoor & Outdoor Allergies

24 Hour Relief of:

Sneezing / Runny Nose Itchy, Watery Eyes Itchy Throat or Nose



PPK-7609-1 0914-1

NO VARNISH ON THIS FLAP

## DYE-FREE FLAVOL

Jm/gm r Antihistamine Cetirizine Hydrochloride Oral Solution

# Allergy

## SEALED WITH PRINTED NECKBAND

## Drug Facts

Active ingredient (in each 5 mL teaspoonful) 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
- sneezin a
- . itching of the nose or throat

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2 years of age

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#### If pregnant or breast-feeding:

- if b reast-feeding; not recommended
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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	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 o 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	ask a doctor	

## Children 24 Hour Allergy

Cetirizine Hydrochloride Oral Solution **Antihistamine** 1 mg/mL

**Dosing Cup** Included



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

\*This product is not manufactured or distributed by UCB Pharma, S.A. CORPORATION BELGIUM, owner of the registered trademark Children's Zyrtec®.





## CHILDRENS 24 HOUR ALLERGY

cetirizine hydrochloride solution

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-102

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength
l	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: A218 C7H19 T)			
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 (sugar free), BANANA	Imprint Code
Contains		

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:41250-102-08	1 in 1 CARTON			
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:41250-102-01	1 in 1 CARTON			
2		240 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	09/08/2011	

## Labeler - Meijer Distribution Inc (006959555)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(41250-102)

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41250-102)	

Revised: 10/2014 Meijer Distribution Inc