CVS PHARMACY CHILDRENS ALLERGY RELIEF- cetirizine hydrochloride solution CVS Pharmacy

CVS Pharmacy[®] 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	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 **1-866-923-4914**

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton

CVS pharmacy®

NDC 59779-276-04

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

Original Prescription Strength

24 HOUR

INDOOR & OUTDOOR ALLERGIES

NEW!

Children's

ALLERGY RELIEF

CETIRIZINE HYDROCHLORIDE ORAL SOLUTION 1mg/mL ANTIHISTAMINE

24 hour relief of:

- Runny nose
- Itchy, watery eyes
- Sneezing
- Itchy throat & nose

Sugar free
Dye free
2 yrs. & older
Dosing cup included

2 FL OZ (60 mL)

Grape Flavor



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

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CVS pharmacy

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LLERGY

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Drug Facts

Active ingredient (in each 5 mL teaspoonful)

Purpose

Četirizine HCI 5 mg.....Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- run ny nose
- · Itchy, watery eyes
- sneezing
- · itching of the nose or throat

Do not use if carton is opened, or if bottle wrap with imprinted safety seal is broken or missing. See bottom panel for expiration date.

Dosing cup included

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

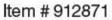






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Made in Israel V-16793





Drug Facts (continued)

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.

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- 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 Polson 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.
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children under 2 years of age	ask a doctor
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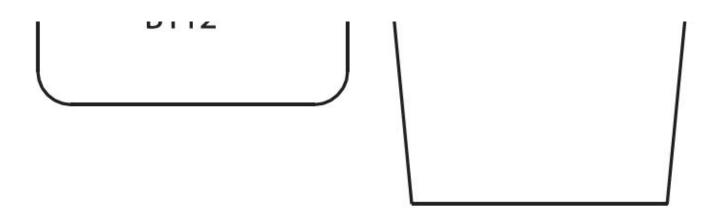
Other information

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

Ouestions? Call 1-866-923-4914

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



CVS PHARMACY CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-276

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of 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) sucralose (UNII: 96K6UQ3ZD4)

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-276-04	1 in 1 CARTON		
1		60 mL in 1 BOTTLE		
2	NDC:59779-276-01	1 in 1 CARTON		

2		240 mL in 1 BOTTLE
3	NDC:59779-276-08	1 in 1 CARTON
3		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 - CVS Pharmacy (062312574)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(59779-276)

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceticals Inc.		206263295	MANUFACTURE(59779-276)	

Revised: 2/2013 CVS Pharmacy