CHILDRENS ALLERGY RELIEF- cetirizine hydrochloride solution Wal-Mart Stores Inc

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: 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)
- dosing cup should be washed and left to air dry after each use
- see bottom panel for expiration date

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: 1-888-287-1915

Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716.

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 49035-088-08

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Compare to Children's Zyrtec® Active Ingredient*

Ages 2+ Children's Allergy Relief Cetirizine Hydrochloride Oral Solution 1 mg/mL Antihistamine

Indoor and Outdoor Allergies

24 Hour Relief of:

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

Grape Flavor

Dosing cup included



CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:49035-088 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	

Inactive Ingredients	
Ingredient Name	Strength
acetic acid (UNII: Q40Q9N063P)	
glycerin (UNII: PDC6 A3C0 OX)	
methylparaben (UNII: A2I8C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sodium acetate anhydrous (UNII: NVG71ZZ7P0)	
sucrose (UNII: C151H8M554)	

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

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49035-088-08	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	04/22/2008	

Labeler - Wal-Mart Stores Inc (051957769)

$\pmb{Registrant - } \textbf{Taro Pharmaceuticals U.S.A., Inc. (145186370)}$

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(49035-088)

Revised: 11/2012 Wal-Mart Stores Inc