

WESTERN FAMILY CHILDRENS ALLERGY RELIEF- cetirizine hydrochloride solution
Western Family Foods Inc

Western Family®
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

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 **1-866-923-4914**

Proudly Distributed by **Western Family Foods, Inc.**
P.O. Box 4057, Portland, OR 97208 U.S.A.

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

**WESTERN
FAMILY®**

INDOOR & OUTDOOR ALLERGIES

Children's

**Allergy
RELIEF**

CETIRIZINE HYDROCHLORIDE
ORAL SOLUTION 1 mg / mL

Antihistamine

**2 years
and older**

Bubblegum
flavored

24 HOUR RELIEF OF:

- ☐ SNEEZING
- ☐ RUNNY NOSE
- ☐ ITCHY, WATERY EYES
- ☐ ITCHY THROAT OR NOSE

4 FL OZ (120 mL)

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S ZYRTEC[®]*



WESTERN FAMILY CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-106
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

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:55312-106-08	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 - Western Family Foods Inc (192166072)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(55312-106)