CHILDRENS CETIRIZINE HYDROCHLORIDE- cetirizine hcl solution Major Pharmaceuticals

Major Pharmaceuticals Children's Cetirizine Hydrochloride Oral Solution Drug Facts

Active ingredient (in each 5 mL)

Cetirizine HCl 5 mg

Purpose

Antihistamine

Uses

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

- runny nose
- sneezing
- itchy, watery eyes
- 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
- find right dose on chart below
- mL = milliliter

	-
adults and children 6 years	5 mL or 10 mL once daily depending upon
and over	severity of symptoms; do not take more than 10
	mL in 24 hours.
adults 65 years and over	5 mL once daily; do not take more than 5 mL in
	24 hours.
children 2 to under 6 years	2.5 mL once daily. If needed, dose can be
of age	increased to a maximum of 5 mL once daily or
	2.5 mL every 12 hours. Do not give more than
	5 mL in 24 hours.
children under 2 years of	ask a doctor
age	
consumers with liver or	ask a doctor
kidney disease	

Other information

- store between 20° to 25°C (68° to 77°F)
- do not use if carton is opened, or if printed neckband is broken or missing
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, artificial grape flavor, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions or comments?

1-800-616-2471

Package/Label Principal Display Panel

COMPARE TO the active ingredient of CHILDREN'S ZYRTEC®

Children's Cetirizine Hydrochloride Oral Solution 1 mg/mL

Antihistamine

ALLERGY

INDOOR & OUTDOOR ALLERGIES

24 HOUR RELIEF OF:

Sneezing / Runny Nose

Itchy, Watery Eyes / Itchy Throat or Nose

4 FL OZ

24 Hour

(118 mL)

2yrs & older

Dosing Cup Included

Dye-Free

Sugar-Free

Grape Flavored Syrup



MAJOR°

COMPARE TO the active ingredient of CHILDREN'S ZYRTEC®*

Children's

Cetirizine

INDOOR & OUTDOOR

ALLERGIES

Dye-Free • Sugar-Free

24 Hour

2yrs & older Dosing Cup Included

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

4 FL OZ

(118 mL)

Grape

Syrup

Flavored

ALLERGIES

ALLERGY

24 HOUR RELIEF OF: Sneezing / Runny Nose Itchy, Watery Eyes / Itchy Throat or Nose



(118 mL)

Grape Havored Syrup



NDC 0904-6765-20

MAJOR®

COMPARE TO the active ingredient of CHILDREN'S ZYRTEC®*

Children's

Cetirizine

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

INDOOR & OUTDOOR

24 HOUR RELIEF OF: Sneezing / Runny Nose Itchy, Watery Eyes / Itchy Throat or Nose



2yrs & older Dosing Cup Included Dye-Free • Sugar-Free

MAJOR° Children's

Cetirizine

Hydrochloride Oral Solution 1 mg/mL Antihistamine ALLERGY

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ALLERGY Antihistamine

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Drug Facts (continued)

- Directions
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 find right dose on chart below
 mL = milliliter

5 mL or 10 mL once daily adults and children depending upon severity of symptoms; do not take more than 10 mL in 24 hours. 6 years and over 5 mL once daily; do not take more than 5 mL in 24 hours. adults 65 years and over 2.5 mL once daily. If needed, dose can be increased to a maximum of 5 mL once daily or 2.5 mL every 12 hours. Do not give more than 5 mL in 24 hours. children 2 to under

children under 2 years of age ask a doctor

ask a doctor consumers with liver or kidney disease

- Other Information

 store between 20° to 25°C (68° to 77°F)

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Inactive ingredients

anhydrous citric acid, artificial grape flavor, propylene glycol, purified water, sodium benzoate, sorbitol

Questions or comments?

Gluten Free

*Major® Children's Cetirizine Hydrochloride Oral Solution 1 mg/mL is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., distributor of Children's Zyrtec®.

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

Distributed by MAJOR® PHARMACEUTICALS 17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152 M-05 REV 07/18 Re-Order No. 700965





LOT NO.

CHILDRENS CETIRIZINE HYDROCHLORIDE

cetirizine hcl solution

Product Information

HUMAN OTC DRUG NDC:0904-6765 Product Type Item Code (Source)

Route of Administration

ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDRO CHLO RIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:0904-6765-20	1 in 1 CARTON	08/22/2018	
l	1	118 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	ANDA204226	08/22/2018	

Labeler - Major Pharmaceuticals (191427277)

Revised: 8/2020 Major Pharmaceuticals