

## **CHILDRENS CETIRIZINE HYDROCHLORIDE- cetirizine hcl solution**

### **Major Pharmaceuticals**

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### **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 and over	5 mL or 10 mL once daily depending upon 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 of age	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 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)
- **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?

**1-800-719-9260**

## **Package/Label Principal Display Panel**

MAJOR<sup>®</sup>

compare to the active ingredient in Children's Zyrtec<sup>®</sup>

children's cetirizine

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

dye-free

sugar-free

2 years and older

grape flavor

dosing cup included

4 fl oz (118 mL)



# CHILDRENS CETIRIZINE HYDROCHLORIDE

cetirizine hcl solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6765
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg in 5 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0904-6765-20	1 in 1 CARTON	08/22/2018	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA204226	08/22/2018	

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 2/2026

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