

CHILDRENS ZYRTEC ALLERGY- cetirizine hydrochloride syrup
Kenvue Brands LLC

Children's ZYRTEC[®]

ALLERGY

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

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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
- in rare cases, you may experience itching after stopping cetirizine. Consult your healthcare provider if this happens.

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. Do not use if bottle wrap imprinted with “Sealed For Your Safety” is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, flavors, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions?

call **1-800-343-7805** (toll-free) or **215-273-8755** (collect).

PRINCIPAL DISPLAY PANEL

NDC 50580-721-05

**Children's
ZYRTEC[®]
ALLERGY**

Cetirizine HCl oral solution

1 mg / ml/antihistamine

Indoor & Outdoor Allergies

2 yrs & older

24 Hour

Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

Dye-Free

Sugar-Free

Alcohol-Free

Bubble Gum Flavor

4 fl oz (118 ml)

Dosing Cup Included



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Drug Facts (continued)

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Active ingredient made in Switzerland
 Distributed by: Kenvue Brands LLC, Summit, NJ 07901
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 www.zyrtec.com 30060664
 Pat. www.kenvuepatz.com
 The trade dress of this ZYRTEC® package is subject to trademark protection.

24 Hour Relief of Sneezing, Runny Nose, Itchy, Watery Eyes, Itchy Throat or Nose. Dye-Free Sugar-Free Alcohol-Free.

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Bubble Gum Flavor 4 fl oz (118 ml) Dosing cup included

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CHILDRENS ZYRTEC ALLERGY			
cetirizine hydrochloride syrup			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-721
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
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	white (Clear, Colorless)	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-721-05	1 in 1 CARTON	07/13/2015	
1		118 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022155	01/20/2009	

Labeler - Kenvue Brands LLC (118772437)