

**CHILDRENS ZYRTEC ALLERGY- cetirizine hydrochloride tablet, orally disintegrating**  
**Kenvue Brands LLC**

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**Childrens Zyrtec Allergy**

***Drug Facts***

**Active ingredient (in each tablet)**

Cetirizine HCl 10 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

Tablet melts in mouth. Can be taken with or without water.

adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 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). Avoid high humidity.
- **do not use if blister unit is torn or broken**

## Inactive ingredients

amino methacrylate copolymer, anhydrous citric acid, colloidal silicon dioxide, crospovidone, flavors, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, sodium bicarbonate, sodium starch glycolate, sucralose

## Questions?

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

## PRINCIPAL DISPLAY PANEL

**New look**

**Same**

**relief**

**Original Prescription Strength**

NDC 50580-782-12

**Children's  
ZYRTEC®**

**ALLERGY**

Cetirizine HCl

orally disintegrating tablets  
**10 mg**/antihistamine

**Indoor &**

**Outdoor**

**Allergies**

**6 yrs & older**

**Sugar-Free • Dye-Free**

**DISSOLVE TABS**

**24**

**Hour**

**Relief of**

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

Actual Size

**Citrus Flavor**

**Melts in your mouth**

**12 ORALLY DISINTEGRATING TABLETS**



## CHILDRENS ZYRTEC ALLERGY

cetirizine hydrochloride tablet, orally disintegrating

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-782
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER</b> (UNII: 905HNO1SIH)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>	CITRUS	<b>Imprint Code</b>	Z10
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-782-12	2 in 1 CARTON	01/20/2014	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-782-24	4 in 1 CARTON	01/20/2014	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-782-01	2 in 1 PACKAGE	01/20/2014	
3		4 in 1 CARTON		
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022578	01/20/2014	

**Labeler** - Kenvue Brands LLC (118772437)