Children's ZYRTEC®

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 carton tape or bottle wrap imprinted "SAFETY SEAL®" 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 50580-730-05

*Children's ZYRTEC® ALLERGY*
*Cetirizine HCl*
*1 mg/ml oral solution*
*antihistamine*

**Indoor & Outdoor Allergies**
*24 hour Relief of*
- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

2 yrs.
& older

Grape
Syrup

*Dye-Free • Sugar-Free*

4 fl oz (118 ml)
Dosing Cup Included
**Drug Facts**

**Active Ingredient**  
Cetirizine hydrochloride  
(in each 5 mL)  
(0.375 g)

**Purpose**  
Antihistamine

**Uses**  
Relief of sneezing, runny nose, itchy, watery eyes, and nose/throat irritation associated with indoor and outdoor allergies.

**Directions**  
Dose according to age and symptoms.

**Uses**  
Indoor & Outdoor Allergies

**Warnings**  
Do not give to children under 2 years of age. Ask a doctor before use if you have asthma or if you have a family history of asthma. Ask a doctor before use if you are taking any other medication.

**Drug Facts (continued)**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
</tr>
</thead>
</table>
| <6 years old | 0.5 mL once daily
| 6-11 years old | 1 mL once daily
| 12 years and older | 2 mL once daily

**Inactive Ingredients**  
Grape flavor, citric acid, sodium benzoate, glycerin, purified water, FD&C Yellow No. 6, FD&C Blue No. 1 Aluminum Lake.

**Questions?**  
Call 1-888-342-7999 (toll-free) or 215-293-9555 (PA only)

**Children's Zyrtec Allergy**

**Product Information**

**Product Type**  
HUMAN OTC DRUG

**Item Code (Source)**  
NDC: 50580-730

**Lot**

**Expiry**

**Children's Zyrtec**
cetirizine hydrochloride syrup

**Active ingredient made in Switzerland**

**Distributed by:**

Michael Czarnecki Healthcare Division of McNeil-PPC, Inc.

Fort Washington, PA 19034 USA

(215) 293-9555

www.zyrtec.com

**USA**

**RS**

**Label**

**Bar Code**

**3 0045 0209 047**

**Barcode**

**4 fl oz (118 ml)**

**Dosing Cup Included**

**The dose strips of this Zyrtec package is resealable to protect it from infants.**
Route of Administration | ORAL

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cetirizine Hydrochloride (UNII: 64O047KTOA) (Cetirizine - UNII:YO7261ME24)</td>
<td>Cetirizine Hydrochloride</td>
<td>5 mg in 5 mL</td>
</tr>
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</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>anhydrous citric acid (UNII: XF417D3PSL)</td>
<td></td>
</tr>
<tr>
<td>propylene glycol (UNII: 6DC9Q167V3)</td>
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<tr>
<td>water (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>sodium benzoate (UNII: OJ245FE5EU)</td>
<td></td>
</tr>
<tr>
<td>sorbitol (UNII: S06T60A25R)</td>
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</tr>
<tr>
<td>sorbitol (UNII: 96K6UQ3ZD4)</td>
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### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
<th>Flavor</th>
<th>GRAPE</th>
<th>Imprint Code</th>
<th>Contains</th>
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</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:50580-730-05</td>
<td>1 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>1 in 1 CARTON</td>
<td>07/13/2015</td>
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<td>2</td>
<td>NDC:50580-730-06</td>
<td>118 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package</td>
<td>07/31/2015</td>
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<tr>
<td>2</td>
<td></td>
<td>2 in 1 PACKAGE</td>
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<td></td>
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<tr>
<td>3</td>
<td>NDC:50580-730-01</td>
<td>30 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package</td>
<td>01/16/2017</td>
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<tr>
<td>3</td>
<td></td>
<td>1 in 1 CARTON</td>
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<td></td>
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<tr>
<td>4</td>
<td>NDC:50580-730-17</td>
<td>3 in 1 PACKAGE</td>
<td>12/03/2018</td>
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<tr>
<td>4</td>
<td></td>
<td>1 in 1 TRAY</td>
<td></td>
<td></td>
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<tr>
<td>4</td>
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<td>118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package</td>
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<td>5</td>
<td>NDC:50580-730-18</td>
<td>2 in 1 PACKAGE</td>
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<td>5</td>
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<td>1 in 1 CARTON</td>
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<tr>
<td>5</td>
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<td>118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package</td>
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### Marketing Information

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<th>Marketing End Date</th>
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<td>NDA</td>
<td>NDA022155</td>
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**Labeler** - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 12/2018

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division