

**CHILDRENS ZYRTEC ALLERGY- cetirizine hydrochloride tablet, orally disintegrating**  
**Johnson & Johnson Consumer Inc.**

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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

### Original Prescription Strength

NDC 50580-782-12

**Children's  
Zyrtec® ALLERGY**

### Cetirizine HCl

orally disintegrating tablets  
**10 mg/antihistamine**

**Indoor + Outdoor  
Allergies**

**Dissolve Tabs**

24  
hour

Relief of

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

6 yrs.  
& older  
10mg each

Citrus Flavor

Actual  
Size

Melts In  
Your Mouth

12 ORALLY DISINTEGRATING TABLETS



30051122

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**When using this product**

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- avoid alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

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**If pregnant or breast-feeding:**

- breast-feeding: not recommended
- if pregnant: ask a health professional before use.

**Drug Facts (continued)**

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**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, amorphous citric acid, colloidal silicon dioxide, croscarmellose, flavors, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, sodium bicarbonate, sodium starch glycolate, sorbitol

**Questions?**

call 1-800-343-7065 (call-free) or 215-273-8755 (collect)

Active ingredient made in Switzerland

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
Children's Allergy Prescription Division  
First Floor, New Brunswick, NJ 08901 USA  
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30051122 / 4001-301-17790.04 www.zyrtec.com

The trade dress of this ZYRTEC® package is subject to trademark protection.

Pat. www.jc.pats.com

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LOT  
EXP

# 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>CROSPVIDONE</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           |                    |

| <b>3</b>                     | 4 in 1 CARTON  |                             |                           |
|------------------------------|--|-----------------------------|---------------------------|
| <b>3</b>                     | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product |                             |                           |
| <b>Marketing Information</b> |  |                             |                           |
| <b>Marketing Category</b>    | <b>Application Number or Monograph Citation</b>        | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| NDA                          | NDA022578  | 01/20/2014                  |                           |

**Labeler** - Johnson & Johnson Consumer Inc. (878046358)

Revised: 6/2023

Johnson & Johnson Consumer Inc.