**ZYRTEC ALLERGY- cetirizine hydrochloride**
**Johnson & Johnson Consumer Inc.**

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**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**

| | |
|---|---|
| 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)
- **do not use if clamshell is opened or if foil inner seal imprinted with "ZYRTEC®" is broken or missing**
- meets USP Dissolution Test 2

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

**Questions?**

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

**PRINCIPAL DISPLAY PANEL**

Original Prescription Strength

NDC 50580-752-01

ZYRTEC ®
ALLERGY

Cetirizine HCl tablets
10 mg /antihistamine

Indoor & Outdoor Allergies

24
hour

Relief of

- Sneezing
- Runny Nose

- Itchy, Watery Eyes
- Itchy Throat or Nose

(Actual Size)
120
Tablets
(contains one bottle of 50 Tablets
and one bottle of 70 Tablets)

Cut To Open

30045795

120 Tablets
10 mg each (contains one bottle of 50 Tablets and one bottle of 70 Tablets)

Original Prescription Strength

NDC 50580-752-01

# ZYRTEC®

Cetirizine HCl tablets
10 mg /antihistamine

ALLERGY

## Indoor & Outdoor Allergies

24 hour Relief of

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

(Actual Size) 

120 Tablets

(contains one bottle of 50 Tablets and one bottle of 70 Tablets)

Cut To Open

30045795

120 Tablets
10 mg each (contains one bottle of 50 Tablets and one bottle of 70 Tablets)

Original Prescription Strength


**ZYRTEC ALLERGY**

cetirizine hydrochloride kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:50580-752 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:50580-752-01 | 1 in 1 PACKAGE | 06/15/2020 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 1 BOTTLE, PLASTIC | 50 |
| **Part 2** | 1 BOTTLE, PLASTIC | 70 |

## Part 1 of 2

## ZYRTEC ALLERGY

cetirizine hydrochloride tablet, film coated

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:50580-726 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **CETIRIZINE HYDROCHLORIDE** (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZINE HYDROCHLORIDE | 10 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | 2 pieces |

| | | | |
|---|---|---|---|
| **Shape** | RECTANGLE (rounded-off rectangular biconvex tablet) | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | ZYRTEC;10;MG |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:50580-726-50 | 1 in 1 PACKAGE | | |
| **1** | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| NDA | NDA019835 | 01/26/2010 | |

## Part 2 of 2

## ZYRTEC ALLERGY

cetirizine hydrochloride tablet, film coated

**Product Information**

| | |
|---|---|
| **Item Code (Source)** | NDC:50580-726 |
| **Route of Administration** | ORAL |

**Active Ingredient/Active Moiety**

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **CETIRIZINE HYDROCHLORIDE** (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZINE HYDROCHLORIDE | 10 mg |

**Inactive Ingredients**

| Ingredient Name | Strength |
|---|---|
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | 2 pieces |
| **Shape** | RECTANGLE (rounded-off rectangular biconvex tablet) | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | ZYRTEC;10;MG |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:50580-726-70 | 1 in 1 PACKAGE | | |
| **1** | | 70 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| NDA | NDA019835 | 01/01/2008 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| NDA | NDA019835 | 06/15/2020 | |

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

Revised: 3/2023 Johnson & Johnson Consumer Inc.