**CETIRIZINE HYDROCHLORIDE 10 MG- cetirizine hydrochloride 10 mg tablet, film coated**
**Contract Pharmacal Corp.**

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**3579**

***Drug Facts***

***Active ingredient (in each tablet)***

Cetirizine Hydrochloride 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

**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 sedatives or tranquilizers.

**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 (1-800-222-1222) right away.

### *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).

hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate, povidone, pregelatinized starch, and titanium dioxide.

1-800-231-4670

DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Manufactured by:
Contract Pharmacal Corp.
165 Oser Avenue
Hauppauge, NY 11788 USA
www.cpc.com

* This product is not manufactured or distributed by Kenvue Brands LLC., the owner of the registered trademark Zyrtec®.

NDC 10267-3579-6
*Compares to Zyrtec®Allergy Original Prescription Strength

Allergy

Cetirizine HCl Tablets, USP

10mg/ Antihistamine

Indoor & Outdoor Allergies

24 Hour

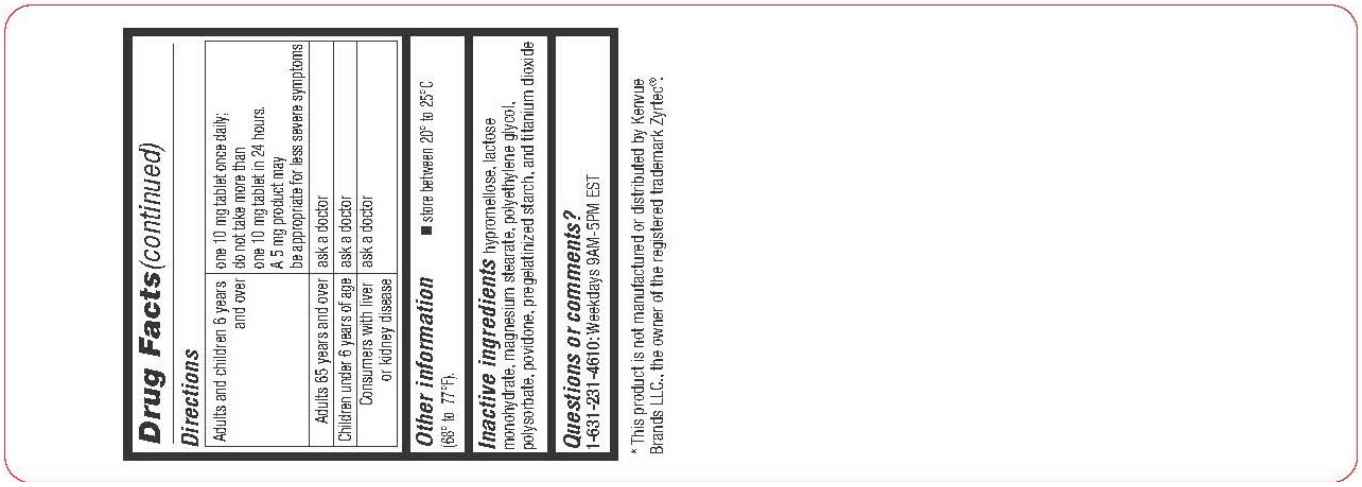
RELIEF OF
• Sneezing
• Runny Nose
• Itchy, Watery Eyes
• Itchy Throat or Nose

365 Tablets

10 mg each


6.375″

INSIDE




# CETIRIZINE HYDROCHLORIDE 10 MG

cetirizine hydrochloride 10 mg tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:10267-3579 |
| **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 |
|---|---|
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **POVIDONE K30** (UNII: U725QWY32X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | ROUND (Biconvex) | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | C;2 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:10267-3579-3 | 1 in 1 CARTON | 12/31/2025 | |
| **1** | | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:10267-3579-7 | 1 in 1 CARTON | 12/31/2025 | |
| **2** | | 60 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **3** | NDC:10267-3579-1 | 1 in 1 CARTON | 12/31/2025 | |
| **3** | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **4** | NDC:10267-3579-6 | 365 in 1 BOTTLE; Type 0: Not a Combination Product | 04/16/2025 | |
| **5** | NDC:10267-3579-4 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 05/31/2025 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA076047 | 04/16/2025 | |

## Labeler - Contract Pharmacal Corp. (057795122)

## Registrant - Contract Pharmacal Corp. (057795122)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Contract Pharmacal Corp. | | 057795122 | pack(10267-3579) , label(10267-3579) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Contract Pharmacal Corp. | | 968335112 | manufacture(10267-3579) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Contract Pharmacal Corp. | | 968334974 | manufacture(10267-3579) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Contract Pharmacal Corp. | | 079157508 | manufacture(10267-3579) |

Revised: 5/2025 Contract Pharmacal Corp.