**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, film coated**
**Proficient Rx LP**

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**Cetrizine HCL Tablet 10 mg**

Drug Facts

**Active ingredient (in each tablet)**

Cetirizine HCl, USP 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**

1. drowsiness may occur
2. avoid alcoholic drinks
3. alcohol, sedatives, and tranquilizers may increase drowsiness
4. 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.

**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° and 25°C (68° - 77°F)
- USP Dissolution Test 3

**Inactive ingredients**

Lactose monohydrate, microcrystalline cellulose, starch (corn), magnesium stearate, hypromellose, polydextrose, polyethylene glycol and titanium dioxide.

**Questions or comments?**

call **1-800-706-5575**, weekdays, 8:30am - 5:00pm Eastern Standard Time

| Manufactured by: | Manufactured for: | Repackaged by: |
|---|---|---|
| Apotex Inc. | Apotex Corp. | Proficient Rx LP |
| Toronto, Ontario | Weston, Florida | Thousand Oaks, CA 91320 |
| Canada M9L 1T9 | 33326 | |

**PRINCIPAL DISPLAY PANEL - 10 mg**

**APOTEX CORP.** NDC 63187-932-15

**Cetirizine 10 mg**

*Cetirizine Hydrochloride Tablets*

*Antihistamine/*Original Prescription Strength

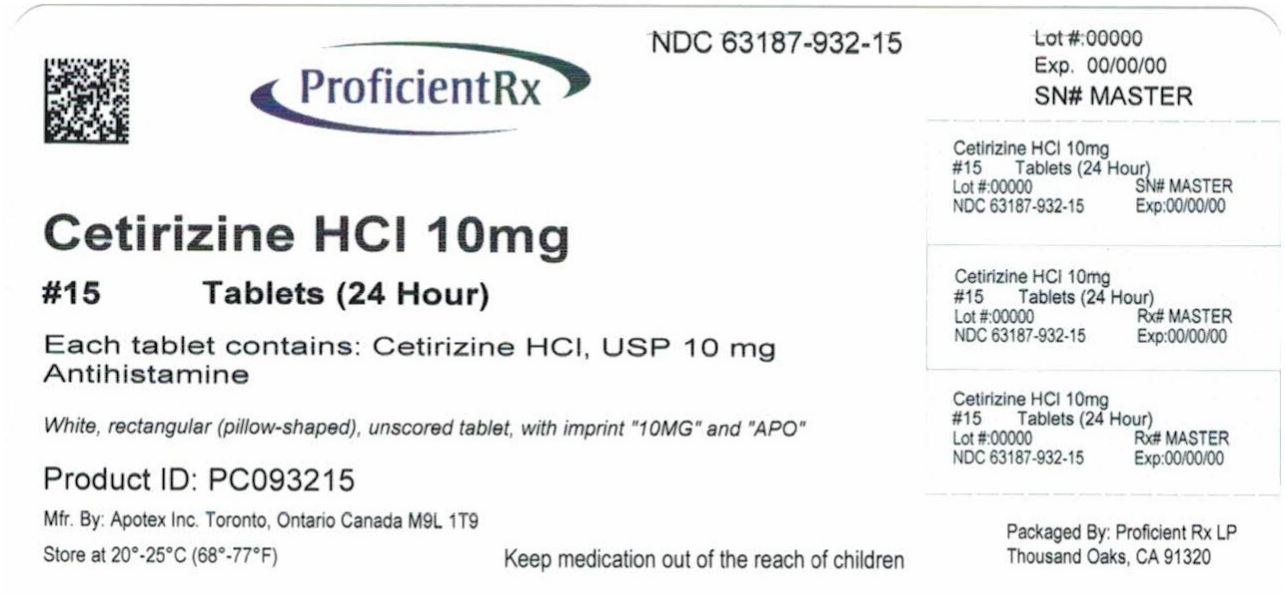
**Indoor & Outdoor Allergies**

**24 hour**

**Relief of**

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

15 count




# CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:63187-932(NDC:60505-2633) |
| **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) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **POLYDEXTROSE** (UNII: VH2XOU12IE) | |
| **POLYETHYLENE GLYCOL 3350** (UNII: G2M7P15E5P) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | WHITE | **Score** | no score |
| **Shape** | RECTANGLE (pillow-shaped) | **Size** | 9mm |

| | | | |
|---|---|---|---|
| **Flavor** | | **Imprint Code** | 10 MG;APO |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:63187-932-15 | 15 in 1 BOTTLE; Type 0: Not a Combination Product | 12/01/2017 | |
| **2** | NDC:63187-932-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2017 | |
| **3** | NDC:63187-932-60 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2017 | |
| **4** | NDC:63187-932-90 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA078317 | 12/27/2007 | |

## Labeler - Proficient Rx LP (079196022)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Proficient Rx LP | | 079196022 | REPACK(63187-932) , RELABEL(63187-932) |

Revised: 11/2019 Proficient Rx LP