

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet**  
**Proficient Rx LP**

-----  
**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**

- 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**

- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.(for bottle cartons/stand-alone labels only)**
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.(for blister cartons only)**
- store between 20° to 25° C (68° to 77° F)

**INACTIVE INGREDIENTS**

corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide

**QUESTIONS?**

call **1-800-406-7984**

**KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION. SEE END PANEL FOR EXPIRATION DATE.**

Distributed by:

Ohm Laboratories Inc.

1385 Livingston Avenue

North Brunswick, NJ 08902

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

**PRINCIPAL DISPLAY PANEL**

†Compare to the active ingredient of Zyrtec®

**NDC 63187-110-90**

**Original Prescription Strength**

**Cetirizine HCl Tablets, 10 mg**

**Antihistamine**

**Allergy**

**Indoor & Outdoor Allergies**

**24 Hour**

**Relief of:**

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

**90 TABLETS 10 mg EACH**

†This product is not manufactured or distributed by McNeil-PPC, Inc., distributor of Zyrtec®. Zyrtec® is a registered trademark of UCB Pharma, S.A.

The image shows a detailed product label for Cetirizine HCl 10mg #90 Tablets (24 Hour). The label features the ProficientRx logo at the top left, a QR code labeled "Scan Here" next to it, and the NDC number 63187-110-90. The product name "Cetirizine HCl 10mg #90 Tablets (24 Hour)" is prominently displayed. Below this, it states "Each tablet contains: Cetirizine HCl, USP 10 mg Antihistamine" and provides a description: "White, rectangle (rounded-off), unscored with imprint code 'R152'". The Product ID is RC011090. The label also includes distribution information: "Dist. By: Ohm Laboratories Inc. North Brunswick, NJ 08901" and storage instructions: "Store at 20°-25°C (68°-77°F)". A warning to "Keep medication out of the reach of children" is present. On the right side, there are three identical blocks of information: "Cetirizine HCl 10mg #90 Tablets (24 Hour)", "Lot #:00000", "SN# MASTER", "NDC 63187-110-90", and "Exp:00/00/00". At the bottom right, there is a QR code and the GTIN: 00363187110901, along with "SN# MASTER", "Exp. 00/00/00", and "Lot #:00000". A vertical barcode on the left side of the label contains the number 63187110901.

**CETIRIZINE HYDROCHLORIDE**

cetirizine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63187-110(NDC:51660-939)
<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>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE (rounded-off)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	RI52
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-110-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	
2	NDC:63187-110-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2021	
3	NDC:63187-110-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077498	12/27/2007	

**Labeler** - Proficient Rx LP (079196022)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Proficient Rx LP		079196022	REPACK(63187-110) , RELABEL(63187-110)

Revised: 6/2022

Proficient Rx LP