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

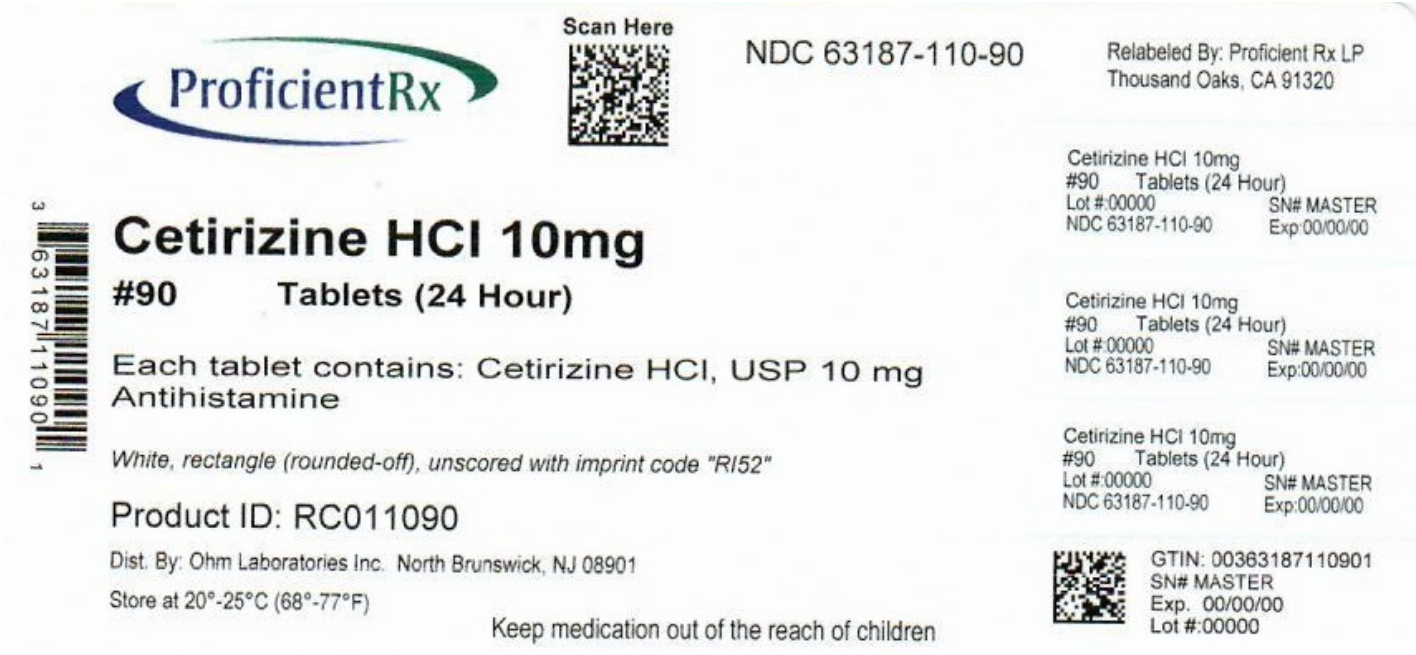
24 Hour

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.



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63187-110(NDC:51660-939)
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
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

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

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

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

Revised: 6/2022 Proficient Rx LP