

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
PD-Rx Pharmaceuticals, Inc.

Cetirizine Hydrochloride

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 SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.**
- 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**

HOW SUPPLIED

Cetirizine HCL 10mg:

10 mg white, rectangle (rounded-off), tablets, debossed "RI52" on obverse and plain on reverse. They are available as follows:

Bottles of 7: NDC 55289-995-07

Bottles of 10: NDC 55289-995-10

Bottles of 30: NDC 55289-995-30

Bottles of 90: NDC 55289-995-90

PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

Cetirizine HCl Tablets, USP 10 mg

ANTIHISTAMINE

Drug Facts

Active Ingredient (in each tablet) Purpose
Cetirizine HCL, USP 10mg.....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 you use if you have liver or kidney disease. Your doctor should determine if you need a different dose.



24 Hour Allergy Relief
Cetirizine HCl
10mg Antihistamine
Indoor and Outdoor Allergies

Relief of: • Sneezing • Runny Nose
• Itchy Watery Eyes
• Itchy Throat or Nose

30 Tablets



3 55289 99530 2



GTIN: 00355289995302
SNO: L22D49000001
EXP: 06/2024
LOT: L22049

Drug Facts (Continued)

Ask a doctor or pharmacist before you 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.

Drug Facts (Continued)

Keep out of the reach of children • in case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions
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- **Children under 6 years of age** ask a doctor
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Drug Facts (Continued)

Other information • Store between 20°-25°C (68°-77°F).
TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.

Inactive ingredients Corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide.

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55289-995(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: 3WJQ0SDW1A)	

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:55289-995-07	7 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/08/2022	
2	NDC:55289-995-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/26/2018	
3	NDC:55289-995-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/26/2018	
4	NDC:55289-995-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/09/2022	

Marketing Information

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

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(55289-995)