

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

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**Cetirizine Hydrochloride Tablets 10 mg**

**Active ingredient (in each tablet)**

Cetirizine HCl 10 mg

**Purpose**

Antihistamine

**Uses**

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

1. runny nose
2. sneezing
3. itchy, watery eyes
4. 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 sedatives or tranquilizers.

**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:**

1. if breast-feeding: not recommended
2. 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**

1. store between 20 - 25°C (68 - 77°F)
2. TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.

**Inactive ingredients**

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

**Questions or comments?**

**1-613-231-4610 Weekdays 9AM-5PM EST**

**Principal Display Panel**

Cetirizine Hydrochloride Tablets 10 mg

Antihistamine

<b>Drug Facts</b>	
<b>Active Ingredient (in each tablet)</b>	<b>Purpose</b>
Cetirizine HCl, 10 mg	Antihistamine
<b>Uses</b>	
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	
<b>Warnings</b>	
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	


 GTIN: 00372789458519  
 SNO: J23B04000001  
 EXP: 04/2025  
 LOT: J23B04

**NDC 72789-458-51**



## Cetirizine HCl

### Tablets **10 mg**

**Antihistamine**  
 Allergy  
 24 Hour Relief

**365 Tablets**  
 TAMPER EVIDENT: DO NOT USE IF  
 SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.

<b>Drug Facts (continued)</b>	
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. <b>Keep out of reach of children.</b>	
In case of overdose, get medical help or contact a Poison Control Center right away 1-(800) 222-1222	
<b>Directions:</b>	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 and children 6 years and over	ask a doctor
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumer with liver or kidney disease	ask a doctor
<b>Other information</b>	
• store at 20° to 25°C (68° to 77°F)	
<b>Inactive Ingredients</b> hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate, povidone, pregelatinized starch, and titanium dioxide	
<b>Question or comments</b>	
1-631-231-4610: Weekdays 9am-5pm EST	

## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72789-458
<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>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	C;2
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72789-458-51	365 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2025	
2	NDC:72789-458-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/29/2025	
3	NDC:72789-458-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/29/2025	
4	NDC:72789-458-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/23/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076047	04/23/2025	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
CONTRACT PHARMACAL CORP.		078666313	manufacture(72789-458)

Revised: 11/2025

PD-Rx Pharmaceuticals, Inc.