

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

Perrigo Cetirizine Hydrochloride Tablets 10 mg Drug Facts

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 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:

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. do not use if printed foil under cap is broken or missing

Inactive ingredients

corn starch, FD&C blue no. 1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

Questions or comments?

1-800-719-9260

Principal Display Panel

Cetirizine Hydrochloride Tablets 10 mg

Antihistamine

Allergy

24 Hour Relief of:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

Original Prescription Strength

Bottle of 300 tablets, NDC: 72789-343-87

Indoor & Outdoor Allergies

<p>Drug Facts</p> <p>Active Ingredient (in each tablet) Cetirizine HCl, 10 mg Purpose Antihistamine</p> <p>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</p> <p>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.</p> <p>Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.</p> <p>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</p> <p>when using this product</p> <ul style="list-style-type: none"> • drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery <p>GTIN: 00372789343303 SNO: K22B60000005 EXP: 06/2024 LOT: K22B60</p>	<p>NDC 72789-343-30</p>  <p>Cetirizine HCl Tablets 10 mg Antihistamine Allergy 24 Hour Relief</p> <p>Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-405-942-3040 v.8.15.0</p> <p>30 Tablets TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.</p>	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>if pregnant or breast-feeding: • if breast-feeding: not recommended if pregnant: ask a health professional before use.</p> <p>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</p> <table border="1"> <tr> <td>Directions:</td> <td>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.</td> </tr> <tr> <td>Adults and children 6 years and over</td> <td>ask a doctor</td> </tr> <tr> <td>adults 65 years and over</td> <td>ask a doctor</td> </tr> <tr> <td>children under 6 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>consumer with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table> <p>Other information • store at 20° to 25°C (68° to 77°F)</p> <p>Inactive Ingredients corn starch, FD&C blue no. 1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p>Question or comments 1-800-719-9260</p>	Directions:	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
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CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC: 72789-343(NDC: 45802-919)
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
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIA CETIN (UNII: XHX3C3X673)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	4H2
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72789-343-87	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078336	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(72789-343)

Revised: 8/2023

PD-Rx Pharmaceuticals, Inc.