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

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 safety seal is broken or missing from bottle.

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

HOW SUPPLIED

Cetirizine HCL 10mg:

10 mgwhite, (oval), tablets, debossed "4H2" on obverse and plain on reverse. They are available as follows:

Bottles of 10: NDC 72789-343-10

Bottles of 30: NDC 72789-343-30

Bottles of 90: NDC 72789-343-90

Principal Display Panel

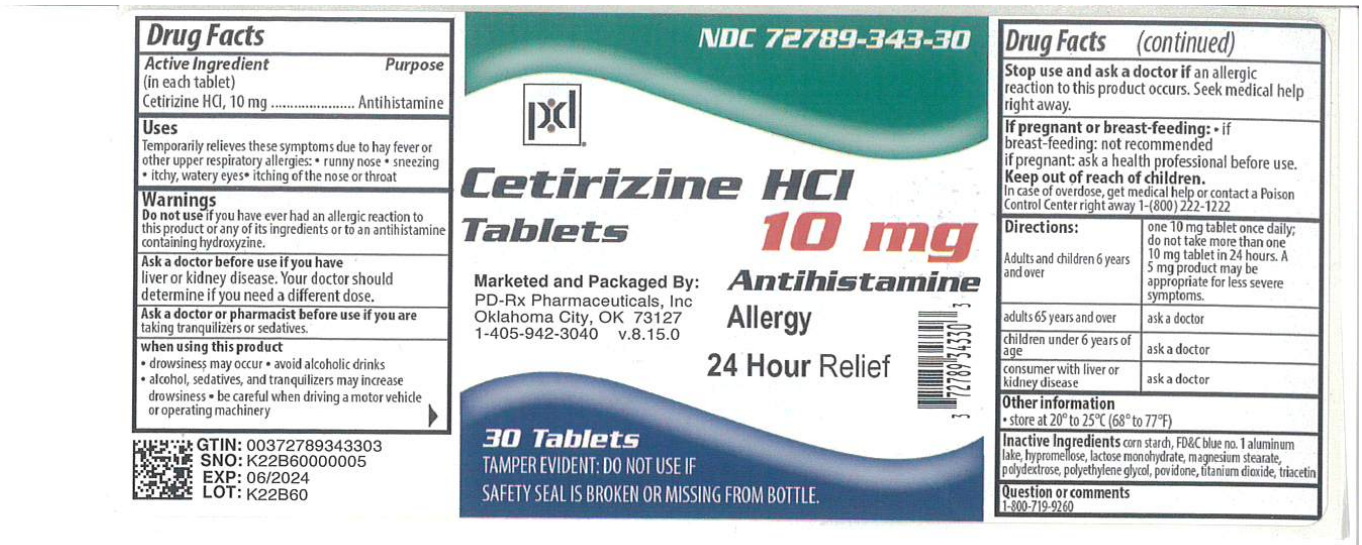
Cetirizine Hydrochloride Tablets 10 mg

Antihistamine

Allergy

24 Hour Relief of:

Indoor & Outdoor Allergies



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: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (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:72789-343-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2023	
2	NDC:72789-343-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2023	
3	NDC:72789-343-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2024	

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: 3/2024 PD-Rx Pharmaceuticals, Inc.