

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Bryant Ranch Prepack**

Cetirizine Hydrochloride Tablets USP, 10 mg, Allergy

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:

store at 20° to 25°C (68° to 77°F)

[See USP Controlled Room Temperature].

Inactive ingredients

Hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide.

Questions?

Call 1-844-874-7464

Manufactured by:

Unique Pharmaceutical Labs.

(A Div. of J. B. Chemicals & Pharmaceuticals Ltd.),
Mumbai 400 030, India

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

M. L. G/1430 Jul. 2020

126406

HOW SUPPLIED

- NDC: 71335-0300-1: 30 Tablets in a BOTTLE
- NDC: 71335-0300-2: 14 Tablets in a BOTTLE
- NDC: 71335-0300-3: 7 Tablets in a BOTTLE
- NDC: 71335-0300-4: 10 Tablets in a BOTTLE
- NDC: 71335-0300-5: 15 Tablets in a BOTTLE
- NDC: 71335-0300-6: 90 Tablets in a BOTTLE
- NDC: 71335-0300-7: 20 Tablets in a BOTTLE
- NDC: 71335-0300-8: 60 Tablets in a BOTTLE
- NDC: 71335-0300-9: 100 Tablets in a BOTTLE

Repackaged/Relabeled by:

Bryant Ranch Prepack, Inc.

Burbank, CA 91504

Cetirizine Hydrochloride 10 mg Tablet



GTIN 00371335030018
 Lot 208620
 Exp 7/25/2026
 SN 0123456789

Drug Facts	
Active Ingredients (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)	
Other Information store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].	
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.	
Inactive Ingredients Hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide.	

NDC 71335-0300-1

**Cetirizine Hydrochloride
Tablets, USP**

10 mg

30 Tablets



Repackaged by:
 Bryant Ranch Prepack, Inc.
 Burbank, CA 91504 USA

Manufactured by:
 Unique
 Pharmaceutical Labs.



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71335-0300(NDC:16571-402)
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White)	Score	no score
Shape	BULLET (Barrel Shaped)	Size	8mm
Flavor		Imprint Code	CTN;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-0300-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2018	
2	NDC:71335-0300-2	14 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2018	
3	NDC:71335-0300-3	7 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
4	NDC:71335-0300-4	10 in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2019	
5	NDC:71335-0300-5	15 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
6	NDC:71335-0300-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2018	
7	NDC:71335-0300-7	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2019	
8	NDC:71335-0300-8	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/13/2021	
9	NDC:71335-0300-9	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	10/01/2009	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-0300) , RELABEL(71335-0300)

Revised: 7/2024

Bryant Ranch Prepack