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

- drowsines may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinary.

Stop use and ask a doctor if an allergic reaction tothis 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

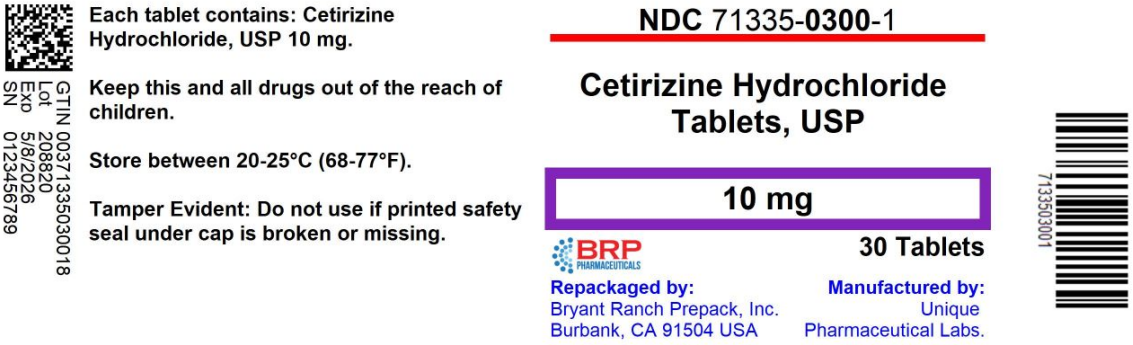
NDC: 71335-0300-9: 100 Tablets in a BOTTLE

Repackaged/Relabeled by:

Bryant Ranch Prepack, Inc.

Burbank, CA 91504

Cetirizine Hydrochloride 10 mg Tablet



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: 3WQ0SDW1A)	
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: 4/2024 Bryant Ranch Prepack