CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Bryant Ranch Prepack

Cetirizine Hydrochloride Tablets USP
5 mg, Allergy

ACTIVE INGREDIENTS (IN EACH TABLET)

Cetirizine HCl USP 5 mg

PURPOSE

Antihistimine

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

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 DOCTOR

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

ASK DOCTOR/PHARMACIST

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

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 Poison Control Center right away. (1-

800-222-1222)

DIRECTIONS

Adults and children 6years and over	1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours
Adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours
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 July 2020

129575

HOW SUPPLIED

NDC: 63629-4914-1: 30 Tablets in a BOTTLE

Cetirizine HCL 5mg Tablet

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63629-4914(NDC:16571-401)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 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**	7mm
Flavor		**Imprint Code**	CTN;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-4914-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/19/2013	

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(63629-4914) , RELABEL(63629-4914)

Revised: 2/2022 Bryant Ranch Prepack