CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablets tablet, film coated

Bryant Ranch Prepack

Cetirizine Hydrochloride Tablets

Drug Facts

Active ingredient (in each tablet)

Cetirizine HCl, 10mg

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

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Warnings

Ask a doctor before use if you have

Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistaminecontaining 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

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

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

children 6 years	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 between 20° to 25°C (68° to 77°F)

Inactive ingredients

hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, starch, titanium dioxide.

Questions?

call **1-888-375-3784**.

HOW SUPPLIED

NDC: 71335-9612-1: 30 Tablets in a BOTTLE

NDC: 71335-9612-2: 14 Tablets in a BOTTLE

NDC: 71335-9612-3: 7 Tablets in a BOTTLE

NDC: 71335-9612-4: 10 Tablets in a BOTTLE

NDC: 71335-9612-5: 15 Tablets in a BOTTLE

NDC: 71335-9612-6: 90 Tablets in a BOTTLE

NDC: 71335-9612-7: 20 Tablets in a BOTTLE

NDC: 71335-9612-8: 60 Tablets in a BOTTLE

NDC: 71335-9612-9: 100 Tablets in a BOTTLE

Cetirizine Hcl 10mg Tablet



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablets tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71335-9612(NDC:43598-811)

Route of Administration ORAL

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
		CETIRIZ INE HYDROCHLORIDE	10 mg	

Inactive Ingredients		
Ingredient Name	Strength	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)		
STARCH, CORN (UNII: O8232NY3SJ)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	7mm
Flavor		Imprint Code	С
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:71335- 9612-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2023			
2	NDC:71335- 9612-2	14 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2023			
3	NDC:71335- 9612-3	7 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2023			
4	NDC:71335- 9612-4	10 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2023			
5	NDC:71335- 9612-5	15 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2023			
6	NDC:71335- 9612-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2023			
7	NDC:71335- 9612-7	20 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2023			
8	NDC:71335- 9612-8	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2023			
9	NDC:71335- 9612-9	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2023			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078343	12/17/2018	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bryant Ranch Prepack		171714327	REPACK(71335-9612), RELABEL(71335-9612)	

Revised: 1/2023 Bryant Ranch Prepack