

CETIRIZINE- cetirizine hydrochloride tablet, film coated
Bryant Ranch Prepack

Major Pharmaceuticals Cetirizine 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:

- 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 between 20-25°C (68-77°F)
- do not use if printed foil under cap is broken or missing

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

Distributed By:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152

HOW SUPPLIED

Cetirizine HCl 10 mg

NDC: 72162-2162-2: 300 Tablets in a Bottle

NDC: 72162-2162-5: 500 Tablets in a Bottle

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

Cetirizine Hcl 10mg Tablets #300



GTIN 00363629106424
Lot LOT123
Exp 06/02/2025
SN 1234567890

Drug Facts	
Active ingredient (in each tablet)	Purpose
Cetirizine HCl 10 mg	Antihistamine
Uses	
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NDC 72162-2162-5

Cetirizine
All Day Allergy Relief

10 mg



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

500 Tablets
Manufactured by:
Major Pharmaceuticals



7216221625

CETIRIZINE

cetirizine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72162-2162(NDC:0904-6717)
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)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYDEXTROSE (UNII: VH2XOU12IE)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

TRIACETIN (UNII: XHX3C3X673)

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:72162-2162-2	300 in 1 BOTTLE; Type 0: Not a Combination Product	02/02/2024	
2	NDC:72162-2162-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/02/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078336	06/29/2018	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(72162-2162) , RELABEL(72162-2162)

Revised: 2/2024

Bryant Ranch Prepack