

**CETIRIZINE HCL- cetirizine hcl capsule**  
**AMERISOURCE BERGEN**

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***Drug Facts***

***Active ingredient (in each capsule)***

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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- 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.

**Directions**

adults and children 6 years and over	one 10 mg capsule once daily; do not take more than one 10 mg capsule 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°-25°C (68°-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- protect from light

**Inactive ingredients**

FD&C yellow #6, gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol, purified water, sodium hydroxide, sorbitan, sorbitol

**Questions or comments?**

call toll free 1-888-235-2466

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**KEEP THIS CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

†All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of ZYRTEC®

Distributed By

**AmerisourceBergen**

**1300 Morris Drive**

**Chesterbrook, PA 19087**

**Questions or Concerns?**

**www.mygnp.com**

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R0419

**Principal Display Panel**

**Compare to ZYRTEC® active ingredient†**

***NDC 46122-613-63***

**All Day Allergy Relief**

**Cetirizine Hydrochloride Capsules, 10 mg/Antihistamine**

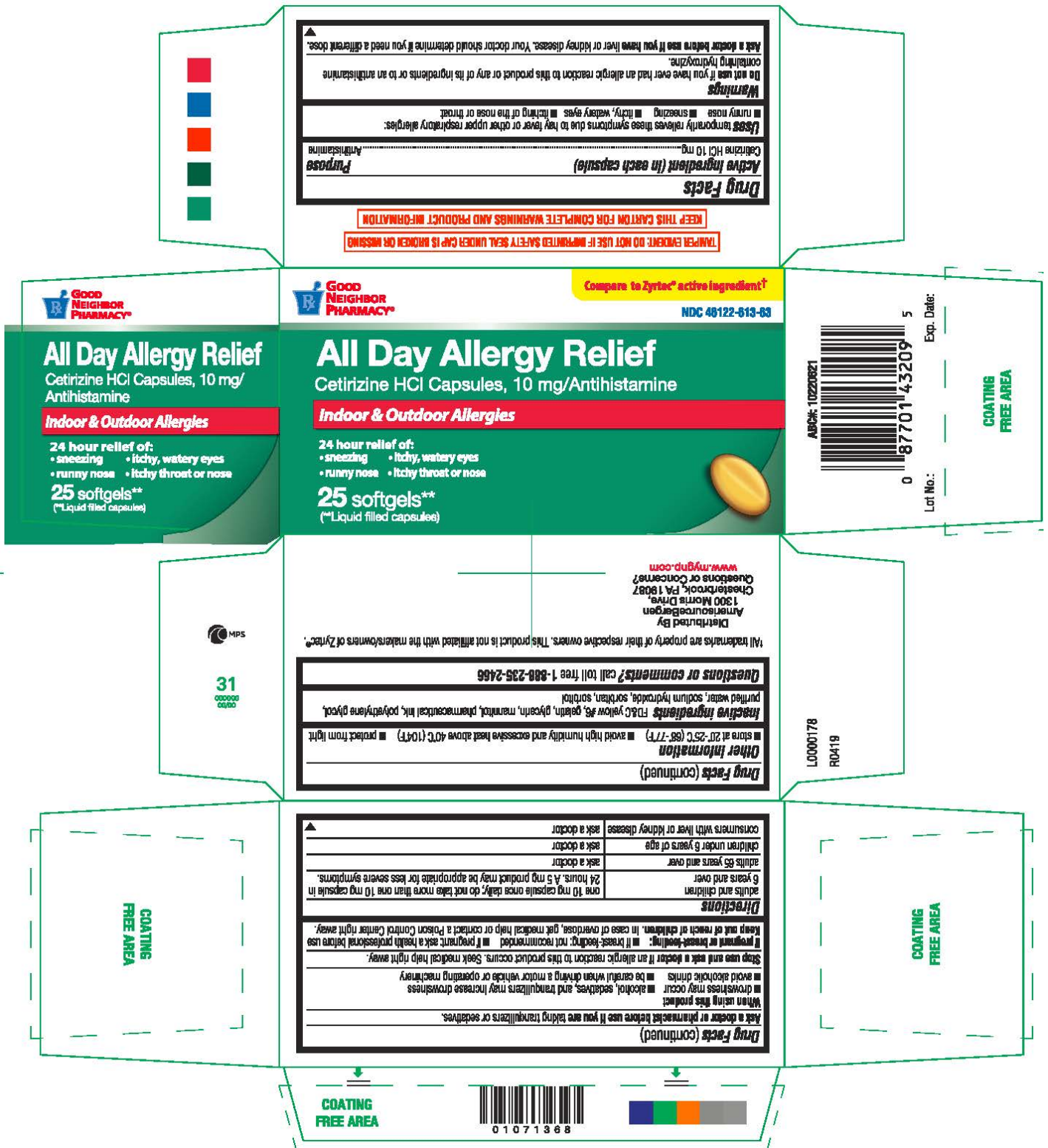
**Indoor & Outdoor Allergies**

**24 Hour Relief of:**

- **Sneezing**
- **Runny nose**
- **Itchy, watery eyes**
- **itchy throat or nose**

**25 SOFTGELS\*\***

(\*\*liquid-filled capsules)



# CETIRIZINE HCL

cetirizine hcl capsule

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46 122-613
<b>Route of Administration</b>	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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

**Product Characteristics**

Color	orange	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	CE1
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-613-63	1 in 1 CARTON	06/18/2019	
1		25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022429	06/18/2019	

**Labeler** - AMERISOURCE BERGEN (007914906)**Registrant** - Bionpharma Inc. (079637826)**Establishment**

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(46122-613)

