

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, film coated**  
**Bionpharma Inc.**

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***Active ingredient (in each tablet)***

Cetirizine Hydrochloride 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**

- 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.

### **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° to 25°C (68° to 77°F).

### **Inactive ingredients**

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

### **Questions or comments?**

call toll-free 1-888-235-2466

This product is not manufactured or distributed by the owners of Zyrtec<sup>®</sup> Tablets.

Distributed by:

#### **BIONPHARMA**

Princeton, NJ 08540

#### **MADE IN INDIA**

Code: TN/Drugs/TN00002222/2006

L0001172

R1025

948006938

### **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

'compare to the active ingredient in Zyrtec<sup>®</sup> Allergy

a+health<sup>™</sup>

original prescription strength

allergy relief  
 cetirizine HCl tablets USP, 10 mg  
 antihistamine  
 6 years and older  
 indoor & outdoor allergies  
 24 hour relief of:

- sneezing
- runny nose
- itchy, watery eyes
- itchy, throat or nose

400 tablets

\*compare to the active ingredient in Zyrtec® Allergy

**A+health™**  
 original prescription strength  
**allergy relief**  
 cetirizine hydrochloride  
 tablets USP, 10 mg  
 antihistamine

6 years and older  
 indoor & outdoor allergies  
 24 hour relief of:

- sneezing
- itchy, watery eyes
- runny nose
- itchy throat or nose

400 tablets

TAMPER-EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

**Drug Facts**

**Active ingredient (in each tablet)** Purpose  
 Cetirizine hydrochloride USP, 10 mg.....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:**  
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 ■ avoid alcoholic drinks  
 ■ alcohol, sedatives, and tranquilizers may increase drowsiness  
 ■ be careful when driving a motor vehicle or operating machinery

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L0001172 R1025 9480006938

3 69452126583 3

UVZ  
 12.5 mm x 30 mm  
 (Lot and Exp online Printing)

PEEL HERE for More Drug Facts

**Drug Facts (Continued)**

**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 tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg strength 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**  
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**Inactive ingredients**  
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**Questions or comments?** call toll-free 1-888-235-2466

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No Text area

T00246R1025

## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69452-465

<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	STARCH, CORN (UNII: O8232NY3SJ)			
	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
	POVIDONE K29/32 (UNII: 390RMW2PEQ)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)			
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
	POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
<b>Product Characteristics</b>				
<b>Color</b>	white (white to off-white)	<b>Score</b>	no score	
<b>Shape</b>	CAPSULE (rounded off rectangular)	<b>Size</b>	9mm	
<b>Flavor</b>		<b>Imprint Code</b>	S;521	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69452-465-81	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2024	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA078862	10/20/2024		

**Labeler** - Bionpharma Inc. (079637826)

**Registrant** - Bionpharma Inc. (079637826)

### Establishment

Name	Address	ID/FEI	Business Operations
OrBion Pharmaceuticals Private Limited		854403569	manufacture(69452-465) , analysis(69452-465) , pack(69452-465) , label(69452-465)

