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

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, lactose monohydrate, povidone, magnesium stearate and opadry white. The components of opadry white are: hydroxypropyl methylcellulose, polyethylene glycol 400, titanium dioxide

Questions or comments?

call toll-free 1-888-235-2466

This product is not manufactured or distributed by the owners of Zyrtec® Tablets.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

'compare to the active ingredient in Zyrtec® Allergy

NDC 69452-465-81

a+health™

original prescription strength

allergy relief

cetirizine HCl tablets USP, 10 mg

antihistamine

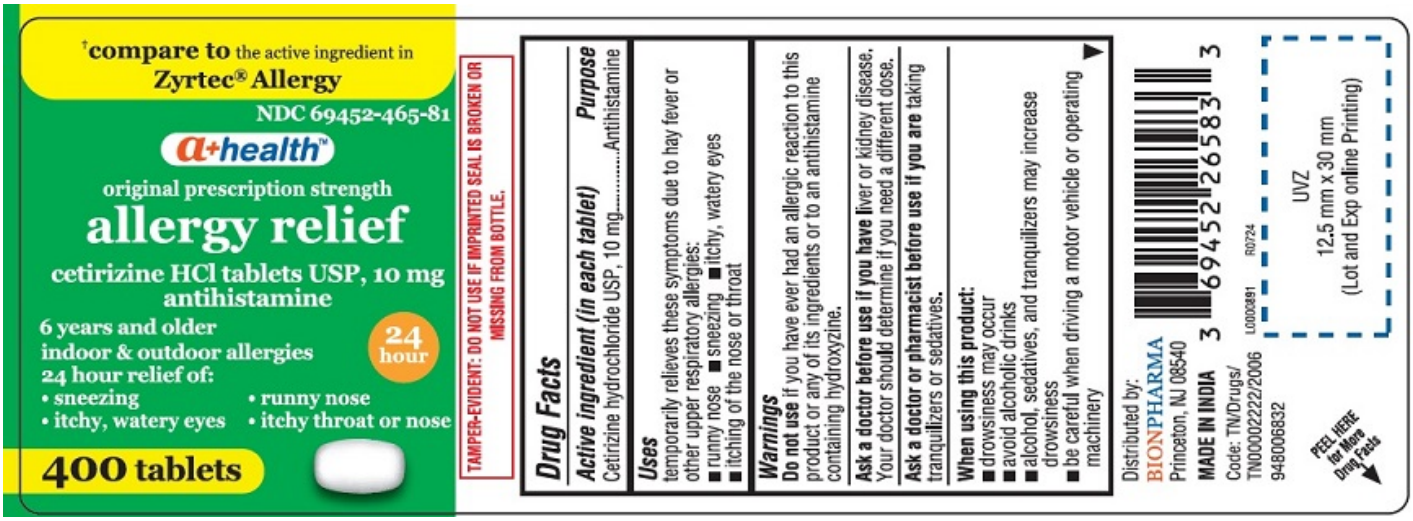
6 years and older

indoor & outdoor allergies

24 hour relief of:

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

400 tablets



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69452-465
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)	
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)	

Product Characteristics

Color	white (white to off-white)	**Score**	no score
Shape	capsule (rounded off rectangular)	**Size**	9mm
Flavor		**Imprint Code**	S;521
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-465-81	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/20/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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)

Revised: 10/2024 Bionpharma Inc.