CETIRIZINE HCL- cetirizine hcl capsule
Bionpharma Inc.

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 20º-25ºC (68º-77ºF)
- avoid high humidity and excessive heat above 40ºC (104ºF)
- 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** (Mon - Fri 9AM - 5PM EST)

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

KEEP THIS CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

Manufactured for:

BIONPHARMA

600 Alexander Road, Princeton, NJ 08540

R0921

L0000534

Principal Display Panel - 65's carton

†**compare to** the active ingredient in **Zyrtec®**

NDC 69452-265-88

a+health ™

cetirizine HCl capsules, 10 mg

antihistamine

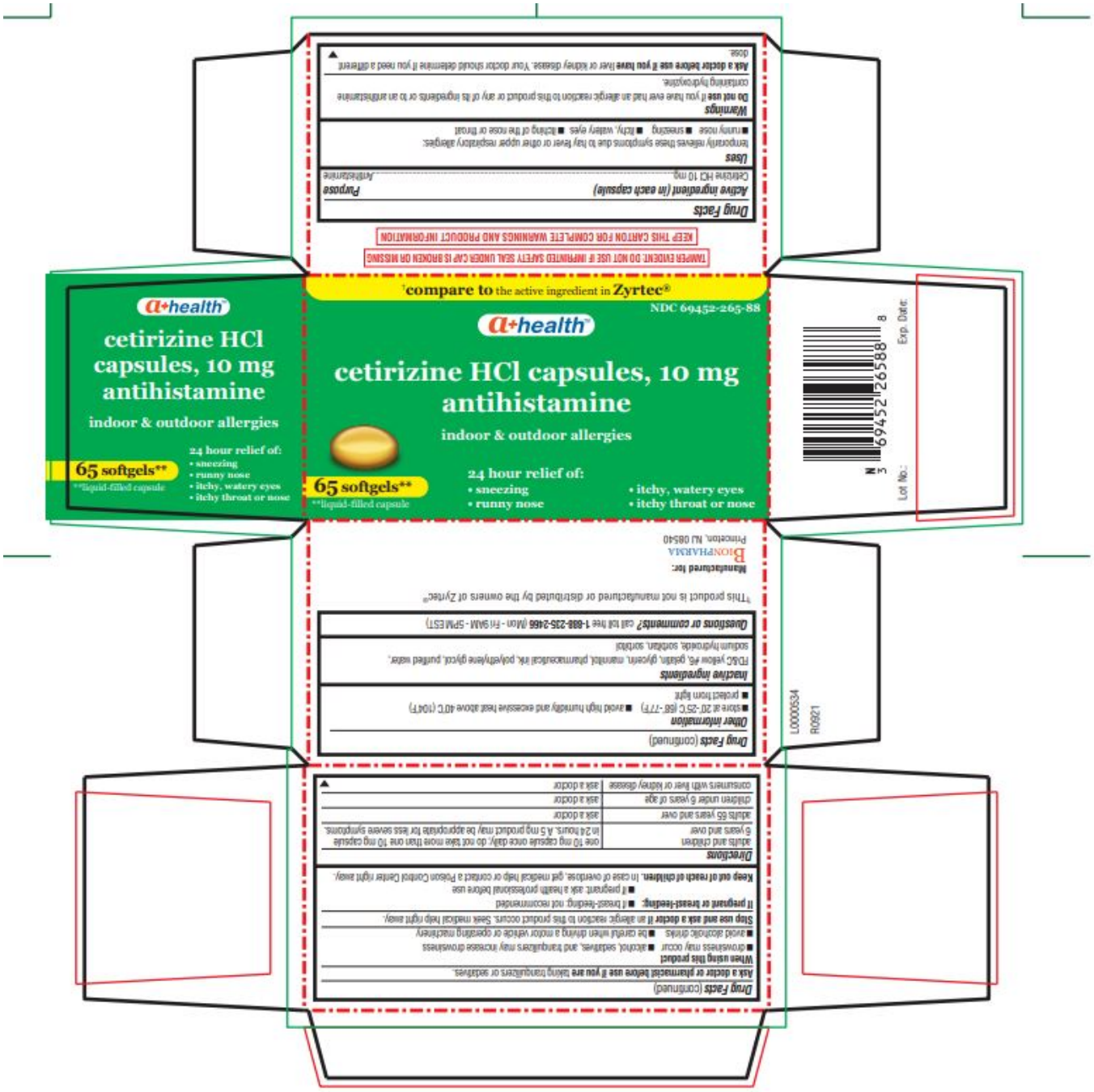
indoor & outdoor allergies

24 hour relief of:

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

65 softgels**

**liquid-filled capsule



CETIRIZINE HCL

cetirizine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69452-265
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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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:69452-265-86	1 in 1 CARTON	05/01/2019	
1		25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:69452-265-15	1 in 1 CARTON	05/01/2019	
2		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:69452-265-88	1 in 1 CARTON	05/01/2019	
3		65 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	05/01/2019	

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(69452-265)

Revised: 12/2022 Bionpharma Inc.