

**CETIRIZINE HCL- cetirizine hcl capsule  
TOP CARE (Topco Associates LLC)**

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***Cetirizine HCl Capsules, 10 mg-publix***

***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 **1-888-423-0139** (Mon - Fri 9AM - 5PM EST)

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

**KEEP THIS CARD FOR COMPLETE WARNINGS AND PRODUCT INFORMATION  
QUALITY GUARANTEED**

**This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.**

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

DISTRIBUTED BY TOPCO ASSOCIATES LLC

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QUESTIONS? 1-888-423-0139  
topcare@topco.com www.topcarebrand.com

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## **Principal Display Panel**

NDC 36800-542-86

TopCare®

health  
COMPARE TO THE ACTIVE  
INGREDIENT IN ZYRTEC®\*

All-Day

Allergy

CETIRIZINE HCl CAPSULES, 10mg  
ANTIHISTAMINE

Indoor & outdoor allergies  
24-hour

RELIEF OF:

Sneezing  
Runny nose  
Itchy, watery eyes  
Itchy throat or nose

actual size

25

SOFTGELS\*\*

\*\*LIQUID-FILLED CAPSULES

**+TopCare**  
health

NDC 36800-54-288

# All-Day Allergy

CETIRIZINE HCl CAPSULES, 10 mg  
ANTIHISTAMINE

INDOOR & OUTDOOR ALLERGIES

**24**  
HOUR

**RELIEF OF:**

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose



actual size

**25**  
SOFTGELS\*\*

\*\*LIQUID-FILLED CAPSULES

COMPARE TO THE ACTIVE  
INGREDIENT IN ZYRTEC\*\*

**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: sneezing, runny nose, 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.

**Drug Facts (continued)**

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, xanthan.

**Questions or comments?**  
call toll free 1-888-423-0139 (Mon - Fri 9AM - 5PM EST)

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

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

**QUALITY GUARANTEED**  
This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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

Scan here for more information or call 1-888-423-0139



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L0000999  
R0924  
Lot No.:  
Exp. Date:

**CETIRIZINE HCL**  
cetirizine hcl capsule

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-542
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	CE1
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-542-86	1 in 1 PACKAGE	11/22/2024	
1		25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:36800-542-15	1 in 1 PACKAGE	11/22/2024	
2		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA022429	11/22/2024	

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**Labeler** - TOP CARE (Topco Associates LLC) (006935977)

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Patheon Softgels Inc.		002193829	manufacture(36800-542)

Revised: 11/2024

TOP CARE (Topco Associates LLC)