

**ALLERGY RELIEF- cetirizine hcl capsule  
Care One (American Sales Company)**

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**Cetirizine Hydrochloride Tablets**

**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

**Warning**

**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 (1-800-222-1222) right away.

## Directions

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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

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## Other Information

- store at 20° to 25°C (68° to 77°F)
- avoid high humidity and excessive heat above 40° C (104° F)
- protect from light

## Inactive Ingredients

Butylated hydroxytolene, gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol 400, purified water, sodium hydroxide, Sorbitan, Sorbitol

## Questions or comments?

**Call 1-877-753-3935 Monday-Friday 9AM-5PM EST**

## Principal Display Panel

Compare to the active ingredient in ZYRTEC® Liquid Gels\*

Allergy Relief

Original Prescription Strength

Cetirizine HCl CAPSULES, 10 mg

Antihistamine

FOR ALLERGY RELIEF OF

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

SOFTGELS

(\*\*LIQUID-FILLED CAPSULES)

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Zyrtec®.

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

DISTRIBUTED BY FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

**Product Label**

Exp. Date:  
 Lot No.:  
 PFD-A523A  
 FC004738

S-949 0518  
 This product is not manufactured or distributed by  
 Michell Consumer Healthcare, distributor of Zyrtec®.

<p><b>Drug Facts (continued)</b></p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p><b>Directions</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">adults and children 6 years and over</td> <td>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.</td> </tr> <tr> <td>adults 65 years and over</td> <td>ask a doctor</td> </tr> <tr> <td>children under 6 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at 20° to 25°C (68° to 77°F)</li> <li>■ avoid high humidity and excessive heat above 40°C (104°F)</li> <li>■ protect from light</li> </ul> <p><b>Inactive ingredients</b> butylated hydroxytoluene, gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol 400, purified water, sodium hydroxide, sorbitan, sorbitol</p> <p><b>Questions or comments?</b>        Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	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	<p>NDC 41520-741-25</p> <p><b>CAREone</b>®</p> <p>Compare to the active ingredient in Zyrtec® Liquid Gels*</p> <p><b>Allergy Relief</b> Original Prescription Strength</p> <p><b>Cetirizine HCl</b> CAPSULES, 10 mg Antihistamine</p> <p><i>Actual Size</i></p> <p><b>FOR ALLERGY RELIEF OF:</b></p> <ul style="list-style-type: none"> <li>• Sneezing</li> <li>• Runny Nose</li> <li>• Itchy, Watery Eyes</li> <li>• Itchy Throat or Nose</li> </ul> <p><b>25 SOFTGELS**</b> (**LIQUID-FILLED CAPSULES)</p> <p></p>	<p>NDC 41520-741-25</p> <p><b>CAREone</b>®</p> <p>Compare to the active ingredient in Zyrtec® Liquid Gels*</p> <p><b>Allergy Relief</b> Original Prescription Strength</p> <p><b>Cetirizine HCl</b> CAPSULES, 10 mg Antihistamine</p> <p><i>Actual Size</i></p> <p><b>FOR ALLERGY RELIEF OF:</b></p> <ul style="list-style-type: none"> <li>• Sneezing</li> <li>• Runny Nose</li> <li>• Itchy, Watery Eyes</li> <li>• Itchy Throat or Nose</li> </ul> <p><b>25 SOFTGELS**</b> (**LIQUID-FILLED CAPSULES)</p> <p></p>	<p><b>Drug Facts</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">Active ingredient (in each capsule)</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Cetirizine HCl 10 mg.....</td> <td>Antihistamine</td> </tr> </table> <p><b>Uses</b></p> <p>temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> <li>■ runny nose</li> <li>■ sneezing</li> <li>■ itchy, watery eyes</li> <li>■ itching of the nose or throat</li> </ul> <p><b>Warnings</b></p> <p><b>Do not use</b> if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.</p> <p><b>Ask a doctor before use if you have</b> liver or kidney disease. Your doctor should determine if you need a different dose.</p> <p><b>Ask a doctor or pharmacist before use if you are</b> taking tranquilizers or sedatives.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ drowsiness may occur</li> <li>■ avoid alcoholic drinks</li> <li>■ alcohol, sedatives, and tranquilizers may increase drowsiness</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> </ul> <p><b>Stop use and ask a doctor if</b> an allergic reaction to this product occurs. Seek medical help right away.</p> <p><b>If pregnant or breast-feeding:</b></p> <ul style="list-style-type: none"> <li>■ if breast-feeding: not recommended</li> <li>■ if pregnant: ask a health professional before use</li> </ul>	Active ingredient (in each capsule)	Purpose	Cetirizine HCl 10 mg.....	Antihistamine
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### CAREONE Allergy Relief Softgels

## ALLERGY RELIEF

cetirizine hcl capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-741
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE -	CETIRIZINE	10 mg

UNII:YO7261ME24)

HYDROCHLORIDE

10 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B6978945GQ)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	

**Product Characteristics**

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	10
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-741-25	1 in 1 BOX	04/30/2018	
1		25 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207235	04/30/2018	

**Labeler** - Care One (American Sales Company) (809183973)

Revised: 10/2023

Care One (American Sales Company)