

**MEDLINE- cetirizine hcl tablet**  
**Medline Industries, LP**

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**033 Cetirizine HCl tablets**

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

Cetirizine HCl, 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 (1-800-222-1222).

### **Directions**

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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

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### **Other information**

store between 20° -25°C (68° -77°F)

### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, opadry white OY-58900, purified water

### **Questions or comments?**

Call toll free **1-800-MEDLINE (633-5463)**

Monday-Friday 9AM-5PM CST

### **Manufacturing Information**

Manufactured for:

Medline Industries, LP


Three Lakes Drive, Northfield, IL 60093 USA

[www.medline.com](http://www.medline.com)

1-800-MEDLINE (633-5463)

REF: OTCM00015

Package Label



NDC: 53329-033-33

\*Compare to the active ingredient in Zyrtec®

Original prescription strength

## Cetirizine HCl Tablets, USP 10 mg

Antihistamine  
Indoor & Outdoor Allergies

- 24 Hour relief of:
  - Sneezing
  - Runny nose
  - Itchy, watery eyes
  - Itchy throat or nose

30

10 mg each

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

**Drug Facts**

**Active ingredient (in each tablet)**  
Cetirizine HCl, 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.

[www.medline.com](http://www.medline.com) Manufactured for: Medline Industries, LP, Three Lakes Drive, Northfield, IL 60063 USA, 1-800-MEDLINE V1 RE22HND

REF: OTCM0015



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**Drug Facts (continued)**

**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 (1-800-422-1222).

**Directions**

<b>Adults and children 6 years and over:</b>	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
<b>Adults 65 years and over</b>	ask a doctor
<b>Children under 6 years of age</b>	ask a doctor
<b>Consumers with liver or kidney disease</b>	ask a doctor

**Other information**  
store between 20° to 25° C (68° to 77° F)

**Inactive ingredients**  
colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, cream, white OY-36900, purified water

**Questions or comments?**  
Call toll free 1-800-MEDLINE (633-5463)  
Monday-Friday 9AM-5PM CST

<b>MEDLINE</b>			
cetirizine hcl tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-033
<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>
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
	MAGNESIUM STEARATE (UNII: 70097M6130)		

<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	

### Product Characteristics

<b>Color</b>	white ((to off white))	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE ((rounded off rectangular shaped))	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	G;4
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-033-33	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
2	NDC:53329-033-38	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	



### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA209274	05/01/2020	

**Labeler** - Medline Industries, LP (025460908)

Revised: 11/2024

Medline Industries, LP