

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet**  
**Medline Industries, LP**

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**652 Cetirizine Hydrochloride**

***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**

- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL BROKEN OR MISSING FROM BOTTLE.**
- store between 20° to 25° C (68° to 77° F)

**Inactive ingredients**

corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide


**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  
Made in USA with domestic and foreign materials  
[www.medline.com/www.curad.com](http://www.medline.com/www.curad.com)  
1-800-MEDLINE (633-5463)  
REF: OTC6817N  
RJ19OHM

# Package Label



NDC: 53329-652-38

Original prescription strength  
**Cetirizine HCl Tablets, USP 10 mg**

Antihistamine  
Indoor & Outdoor Allergies

24 Hour relief of:

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

**90** Tablets

**10 mg** each

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

**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.

**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** ■ 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**  
See carton for complete list of inactive ingredients

**Questions or comments?**  
Call toll free 1-800-MEDLINE (633-5463)  
Monday-Friday 9AM-5PM CST  
www.medline.com Packaged in the USA with U.S. and Foreign Components for: Medline Industries LP, Three Lakes Drive, Northfield, IL 60083 USA. Y1166220HM 1-800-MEDLINE

REF:OTC6817N



XXXXXXX

LOT
EXP

Non-Varnish Area

## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-652
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE (Rounded Off)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	R152
<b>Contains</b>			

### Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-652-38	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077498	12/27/2007	

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

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

Revised: 12/2022

Medline Industries, LP