## 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**

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° -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**

Manufactrued for:

Medline Industries, LP

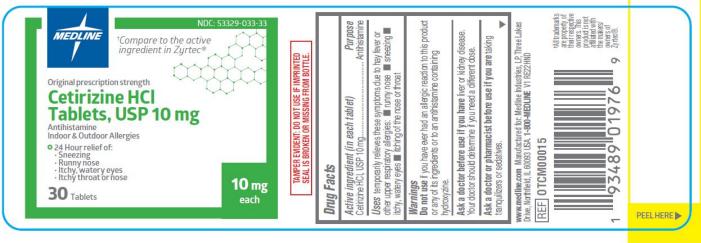
Three Lakes Drive, Northfield, IL 60093 USA

www.medline.com

1-800-MEDLINE (633-5463)

REF: OTCM00015

## **Package Label**



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### **MEDLINE**

cetirizine hcl tablet

Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-033				
Route of Administration	ORAL						

l	Active Ingredient/Active Moiety		
l	Ingredient Name	<b>Basis of Strength</b>	Strength
	CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE HYDROCHLORIDE	10 mg

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

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

P	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**

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

# Labeler - Medline Industries, LP (025460908)

Revised: 11/2024 Medline Industries, LP