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

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#### **033 Cetirizine HCI 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 20º -25ºC (68º -77ºF)

## Inactive ingredients

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

## **Questions or comments?**

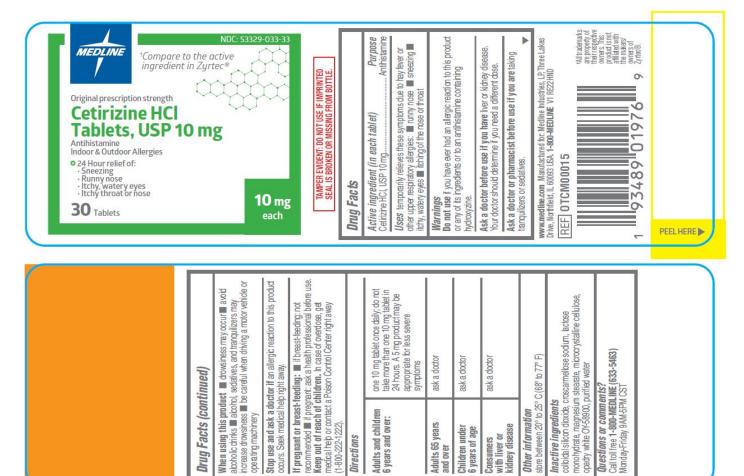
Call toll free 1-800-MEDLINE (633-5463)

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



MEDLINE					
cetirizine hcl tablet					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:53329-033	
Route of Administration	ORAL				
• ·· • • • · · · •	•• • •				
Active Ingredient/Active	Molety				
Ingr	edient Name		Basis of Str	ength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)			CETIRIZ INE HYDROCHLORIDE		10 mg
· · · · · · · · · · · · · · · · · · ·					
Inactive Ingredients					
Ingredient Name					rength
SILICON DIOXIDE (UNII: ETJ7Z6X	BU4)				
MAGNESIUM STEARATE (UNII: 70	007M6120)				

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)								
ACTOSE MON	IOHYDRATE	(UNII: EWQ57Q8	8I5X)					
Product Ch	aracteris	tics						
Color white ((to off white))				Score no		no score		
hape	RECTANGLE	((rounded off r	ectangular shaped	))	Size		9mm	
lavor					Imprint Code		G;4	
Contains								
Packaging								
tem Cod		_	Description	C	ting Start ate		eting End Date	
NDC:53329-0 33	33- 30 in 1 Product	BOTTLE; Type (	): Not a Combinatio	on 05/01/2020	)			
NDC:53329-0	33- 90 in 1 Product		): Not a Combinatio	on 05/01/2020	)			
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# **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: 9/2022

Medline Industries, LP