MEDLINE- cetirizine hcl tablet Medline Industries, LP

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?

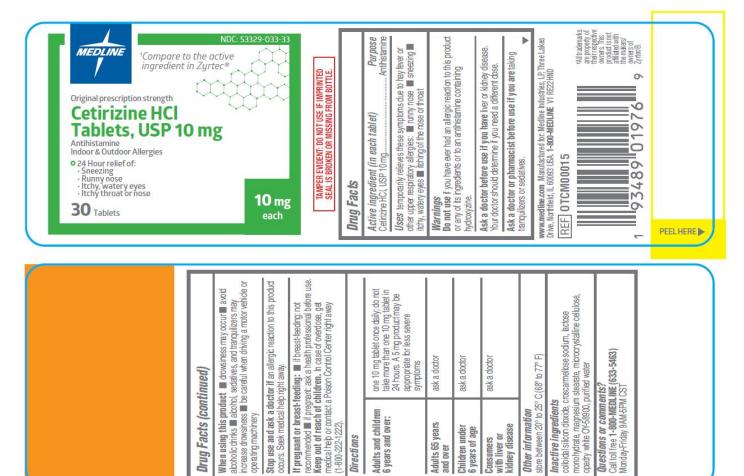
Call toll free 1-800-MEDLINE (633-5463)

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
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)			CETIRIZ INE HYDROCHLORIDE		10 mg
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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