

MEDLINE- cetirizine hcl tablet
Medline Industries, LP

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

Manufactured for:

Medline Industries, LP


Three Lakes Drive, Northfield, IL 60093 USA

www.medline.com

1-800-MEDLINE (633-5463)

REF: OTCM00015

Package Label



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 Tablets

NDC: 53329-033-33

¹Compare to the active ingredient in Zyrtec®



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 10mg.....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 Manufactured for: Medline Industries, LP Three Lakes Drive, Wauwatosa, WI 53093 USA. 1-800-MEDLINE (V1 RE22)HND

[REF: OTCW00015]



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¹All trademarks are property of their respective owners. This product is not identical with the look and feel of Zyrtec®.

<p>Drug Facts (continued)</p>	
<p>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</p>	
<p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p>	
<p>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).</p>	
<p>Directions</p>	
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<p>Other information</p> <p>store between 20° to 25° C (68° to 77° F)</p>	
<p>Inactive ingredients</p> <p>colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, opadry white 0458900, purified water</p>	
<p>Questions or comments?</p> <p>Call toll free 1-800-MED-LINE (633-5463) Monday-Friday 9AM-5PM CST</p>	

MEDLINE

cetirizine hcl tablet

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE 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: M28OL1HH48)	
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			

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: 9/2022

Medline Industries, LP