

CETIRIZINE- cetirizine tablet
Contract Pharmacy Services-PA

HIGHLIGHTS OF PRESCRIBING INFORMATION

Cetirizine 10mg 680

"These highlights do not include all the information needed to use" "see full prescribing information for"
"Initial U.S. Approval"

----- **DOSAGE AND ADMINISTRATION** -----

adults and children 6 years and over (4)
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. (4)
adults 65 years and over (4)
ask a doctor (4)
children under 6 years of age (4)
ask a doctor (4)
consumers with liver or kidney disease (4)
ask a doctor (4)

----- **INDICATIONS AND USAGE** -----

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: (6)

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat (6)

Revised: 2/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

Cetirizine HCL 10MG

Antihistamine

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)

corn starch, FD&C blue no. 1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

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)

CETIRIZINE
10 MG TAB #30



345802919878

LOT: xxx
PILL ID: 4H2
EXP: 04/18/19
PERRIGO

Packaged By: Contract Pharmacy Services-PA
125 Titus Ave, Suite #200, Warrington, PA 18976

Adults and children 6 years
and over: one 10mg tablet
once daily; do not take
more than one tablet in 24
hours.



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Store between 20-25°C (68-77°F)

Each tablet contains Cetirizine HCL 10mg

CPS NDC: 67046-680-30

CETIRIZINE

cetirizine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-680(NDC:45802-919)
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
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	4H2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-680-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078336	02/14/2018	

Labeler - Contract Pharmacy Services-PA (945429777)

Establishment

Name	Address	ID/FEI	Business Operations
Coupler Enterprises Inc.		945429777	repack(67046-680)