

CETIRIZINE- cetirizine hydrochloride tablet, film coated

Major Pharmaceuticals

Major Pharmaceuticals Cetirizine Drug Facts

Active ingredient (in each tablet)

Cetirizine HCl 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)
- do not use if printed foil under cap is broken or missing

Inactive ingredients

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

Questions or comments?

1-800-616-2471

Keep this and all drugs out of the reach of children.

This Unit Dose package is not child resistant and is Intended for Institutional Use Only.

Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268 USA

www.major-rugby.com

Principal Display Panel

MAJOR®

NDC 0904-7510-61

Unit Dose

Original Prescription Strength

Cetirizine

Hydrochloride Tablets

10 mg

Antihistamine

100 TABLETS (10 x 10)

MAJOR[®]

NDC 0904-7510-61

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Hydrochloride Tablets

10 mg**Antihistamine****100 TABLETS (10 x 10)****MAJOR[®]****Drug Facts****Active ingredient (in each tablet)****Purpose**

Cetirizine HCl 10 mg.....Antihistamine

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■ 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**

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NDC # 0904-6717, Major[®] Pharmaceuticals

Distributed by:
MAJOR[®] PHARMACEUTICALS
 Indianapolis, IN 46268 USA
 www.major-rugby.com
 LBLN0295-01

Rev. 03/25 M-05 Re-order No. 303077



(01)00309047510610

CETIRIZINE

cetirizine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7510(NDC:0904-6717)
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)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRACETIN (UNII: XHX3C3X673)	

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:0904-7510-61	100 in 1 CARTON	04/07/2025	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA

ANDA078336

04/07/2025

Labeler - Major Pharmaceuticals (191427277)

Revised: 4/2025

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