

# **CETIRIZINE- cetirizine hydrochloride tablet, film coated**

## **Major Pharmaceuticals**

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### **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?**

**1-800-719-9260**

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Cartons of 100 film-coated tablets (10 film-coated tablets each blister pack x 10), NDC 0904-7510-61

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep this and all drugs out of the reach of children.

**Packaged and Distributed by:**

**MAJOR® PHARMACEUTICALS**

Indianapolis, IN 46268 USA

Refer to package label for Distributor's NDC Number

Rev. 10/24	M-05	Re-Order No. 700885
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**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<sup>®</sup>**

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The drug product contained in this package is from NDC # 0904-6717, Major<sup>®</sup> Pharmaceuticals

Distributed by:  
**MAJOR<sup>®</sup> 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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7510(NDC:0904-6717)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:Y07261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	4H2
<b>Contains</b>			

### 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
ANDA	ANDA078336	04/07/2025	

