

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

## **Major Pharmaceuticals**

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### **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**

## Principal Display Panel

MAJOR<sup>®</sup>

Compare to active ingredient in Zyrtec<sup>®</sup>

Original Prescription Strength

Cetirizine

Hydrochloride Tablets, 10 mg/Antihistamine

All Day Allergy Relief

# INDOOR & OUTDOOR ALLERGIES

## 24 HOUR RELIEF OF:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

Actual Size

30 TABLETS 10 mg EACH



## CETIRIZINE

cetirizine hydrochloride tablet, film coated

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg
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<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<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: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

<b>Product Characteristics</b>			
<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>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6717-41	14 in 1 CARTON	06/29/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-6717-43	1 in 1 CARTON	07/03/2018	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0904-6717-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/03/2018	
4	NDC:0904-6717-72	1 in 1 CARTON	07/03/2018	
4		300 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0904-6717-60	1 in 1 CARTON	07/03/2018	
5		100 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0904-6717-86	1 in 1 CARTON	07/03/2018	
6		90 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0904-6717-46	1 in 1 CARTON	07/03/2018	
7		30 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078336	06/29/2018	

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 11/2022

Major Pharmaceuticals