

# **CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride tablet**

## **A-S Medication Solutions**

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### **Cetirizine Hydrochloride Tablets USP 10 mg (ALLERGY RELIEF)**

#### ***Drug Facts***

##### ***Active ingredient (in each tablet)***

Cetirizine hydrochloride 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° to 25°C (68° to 77°F)
- **TAMPER EVIDENT: DO NOT USE IF SEAL OVER BOTTLE OPENING IS BROKEN OR MISSING**

***Inactive ingredients***

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

***Questions?***

call **1-800-206-7821**

Manufactured for: Northstar Rx LLC

Memphis, TN 38141

Manufactured by: Aurobindo Pharma Limited

Hyderabad-500 090, India

Code: TS/DRUGS/19/1993

Issued: 05/2024

## HOW SUPPLIED

Product: 50090-6950

NDC: 50090-6950-0 30 TABLET in a BOTTLE

NDC: 50090-6950-1 90 TABLET in a BOTTLE

## Cetirizine Hydrochloride



## CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-6950(NDC:16714-799)
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
SILICA (UNII: ETJ7Z6XBU4)	

<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>PEG-8</b> (UNII: B697894SGQ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE (White to Off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	X;36
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-6950-0	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/19/2023	
2	NDC:50090-6950-1	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/28/2026	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090760	08/05/2015	

**Labeler -** A-S Medication Solutions (830016429)

### Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-6950) , REPACK(50090-6950)

Revised: 1/2026

A-S Medication Solutions