# CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablets tablet, film coated

Strategic Sourcing Services LLC

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**Cetirizine Hydrochloride Tablets** 

#### **Drug Facts**

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

Cetirizine HCl, 10mg

#### **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

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## **Warnings**

**Do not use if** you have ever had an allergic reaction to this product or any of its ingredients or to an antihistaminecontaining 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.

#### **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)

## **Inactive ingredients**

hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, starch, titanium dioxide.

#### Questions?

call **1-888-375-3784**.

#### PRINCIPAL DISPLAY PANEL

300 ct Carton



## **Principal Display Panel**

300 ct Container label



### **CETIRIZINE HYDROCHLORIDE**

cetirizine hydrochloride tablets tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1007	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE HYDROCHLORIDE	10 mg	

Inactive Ingredients			
Ingredient Name	Strength		
HYPROMELLOSES (UNII: 3NXW29V3WO)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POVIDONE (UNII: FZ989GH94E)			
STARCH, CORN (UNII: O8232NY3SJ)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	7mm
Flavor		Imprint Code	С
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:70677- 1007-3	1 in 1 CARTON	05/05/2023	01/31/2027		
1		90 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:70677- 1007-1	1 in 1 CARTON	05/05/2023	07/31/2026		
2		30 in 1 BOTTLE; Type 0: Not a Combination Product				
3	NDC:70677- 1007-2	1 in 1 CARTON	05/05/2023	02/28/2027		
3		60 in 1 BOTTLE; Type 0: Not a Combination Product				
4	NDC:70677- 1007-4	1 in 1 CARTON	05/05/2023	02/28/2027		
4		300 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	ANDA078343	05/12/2022	02/28/2027

## **Labeler -** Strategic Sourcing Services LLC (116956644)

Revised: 7/2025 Strategic Sourcing Services LLC