

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablets tablet, film coated

Strategic Sourcing Services LLC

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 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.

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

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	
HYPROMELLOSES (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I3O)				
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	C	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1007-3	1 in 1 CARTON	05/05/2023	
1		90 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70677-1007-1	1 in 1 CARTON	05/05/2023	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70677-1007-2	1 in 1 CARTON	05/05/2023	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:70677-1007-4	1 in 1 CARTON	05/05/2023	
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	

Revised: 4/2023

Strategic Sourcing Services LLC