CETIRIZINE- cetirizine hydrochloride tablet, film coated Major Pharmaceuticals

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	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24
over	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	ask a doctor
disease	

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

Distributed By:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233 Livonia, MI 48152

Principal Display Panel

Cetirizine Hydrochloride Tablets 10 mg

100 Tablets



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CETIRIZINE

cetirizine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6717
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

CETIRIZINE HYDRO CHLO RIDE (UNII: 640047KTOA) (CETIRIZINE -	
LINII-VO 726 1ME24)	

CETIRIZINE HYDROCHLORIDE

10 mg

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	10 mm	
Flavor		Imprint Code	4H2	
Contains				

l	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:0904-6717-61	100 in 1 CARTON	06/29/2018		
ı	1	$1\ \text{in}\ 1\ \text{BLISTER}$ PACK; Type $0\ :$ Not a Combination Product			

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

Labeler - Major Pharmaceuticals (191427277)

TRIACETIN (UNII: XHX3C3X673)

Registrant - Major Pharmaceuticals (191427277)

Revised: 12/2020 Major Pharmaceuticals