

CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet
Apotheca Inc.

Cetirizine 10mg Tablets, Allergy Tablets DRUG FACTS

ACTIVE INGREDIENT

(in each Tablet)
Cetirizine HCl 10mg

PURPOSE

ANTI-HISTAMINE
24 Hour Relief of Indoor and Outdoor Allergies

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 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.
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 and inactive ingredients

Other information

- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, and triacetin

Questions

Call 1-800-262-5244

Monday through Friday 9AM – 2PM MST

Distributed by:

RejuviLife, Phoenix, AZ

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PACKAGE LABEL AND PRINCIPAL DISPLAY PANEL

NDC 12634-987-71

CETIRIZINE HCl

Antihistamine

Indoor and Outdoor Allergies

24 Hour Relief of Sneezing, Runny Nose, Itchy,

Watery Eyes, Itchy Throat or Nose.

Allergy Tablets

RejuviLife

30 Tablets

10 MG

NDC 12634-987-71

CETIRIZINE HCl

Antihistamine
Indoor & Outdoor Allergies
24 Hour Relief of Sneezing, Runny Nose, Itchy,
Watery Eyes, Itchy Throat or Nose

Allergy Tablets



RejuviLife

30 Tablets 10MG

Drug Facts	Purpose
Active Ingredient (in each tablet) Cetirizine HCl 10mg	Antihistamine
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: * runny nose * sneezing * itchy nose or throat * itchy, watery eyes	
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 sedatives or tranquilizers	
When using this product * you may get drowsy * 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, * breast-feeding, not recommended * pregnant, ask a doctor before use Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions * do not exceed 1 tablet in 24 hours * adult and children 6 years and over (one tablet every 24 hours) * 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 at controlled room temperature 20-25 C (68-77 F)	
Inactive ingredients: Lactose monohydrate, microcrystalline cellulose, starch (corn), magnesium stearate, hypromellose, polyethylene glycol and titanium dioxide	
Questions or comments? Call 1-800-366-5555, weekdays, 8:00am-5:00pm Eastern Standard Time	
Exp. Date:	Mfg. by Mylan Morgantown, WV 26505
Lot #:	Dist. by Rejuvillife, Phoenix, AZ

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12634-987(NDC:0378-3637)
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (WHITE)	Score	no score
Shape	BULLET (Barrel Shaped)	Size	8mm
Flavor		Imprint Code	M;C37
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12634-987-96	6 in 1 BOTTLE, PLASTIC		
2	NDC:12634-987-97	7 in 1 BOTTLE, PLASTIC		
3	NDC:12634-987-00	10 in 1 BOTTLE, PLASTIC		
4	NDC:12634-987-80	20 in 1 BOTTLE, PLASTIC		
5	NDC:12634-987-71	30 in 1 BOTTLE, PLASTIC		
6	NDC:12634-987-50	50 in 1 BOTTLE, PLASTIC		
7	NDC:12634-987-01	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076677	01/01/2010	

Labeler - Apotheca Inc. (051457844)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Inc.		051457844	repack, relabel

Revised: 4/2010

Apotheca Inc.