CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet A-S Medication Solutions

Cetirizine Hydrochloride Tablets USP, 10 mg, Allergy

ACTIVE INGREDIENTS

Active Ingredients (in each tablet)

Purpose

Cetirizine HCl USP 10 mg......Antihistimine

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 DOCTOR

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

ASK DOCTOR/PHARMACIST

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

WHEN USING THIS PRODUCT

- drowsines may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinary.

STOP USE

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	one 10 mg tablet once daily, do not take more than one 10 mg tablet in		
6	24 hours. A 5 mg product may be appropriate for less severe		
years and over	symptoms.		
Adults 65 years and Ask a doctor			
over			
Children under 6	Ask a doctor		
years of age			
Consumers with	Ask a doctor		
liver or kidney			
disease			

OTHER INFORMATION

store at 20° to 25°C (68° to 77°F)

[See USP Controlled Room Temperature]

INACTIVE INGREDIENTS

Hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide.

QUESTIONS?

Call 1-866-562-4597

Manufactured by:

Unique Pharmaceutical Labs.

(A Div. of J. B. Chemicals & Pharmaceuticals Ltd.), Mumbai 400 030, India

Distributed by:

Rising Pharmaceuticals, Inc. Saddle Brook, NJ 07663

M. L. G/1430 May 2018

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Cetirizine Hydrochloride



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-1089(NDC:16571-402)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CETIRIZINE HYDRO CHLO RIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII: YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg	

Inactive Ingredients			
Ingredient Name	Strength		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)			
magnesium stearate (UNII: 70097M6I30)			
starch, corn (UNII: O8232NY3SJ)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)			
titanium dioxide (UNII: 15FIX9 V2JP)			

Product Characteristics			
Color	WHITE (White)	Score	no score
Shape	BULLET (Barrel Shaped)	Size	8 mm
Flavor		Imprint Code	CTN;10
Contains			

Pac	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

				J	
1	NDC:50090-1089-0	14 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	08/31/2019	
2	NDC:50090-1089-3	90 in 1 BOTTLE; Type 0: Not a Combination Product 11/28/2014			
3	NDC:50090-1089-1	30 in 1 BOTTLE; Type 0: Not a Combination Product			
4 NDC:50090-1089-2 100 in 1 BOTTLE; Type 0: Not a Combination Product 11/28/2014					
N	Aarketing Info	rmation			

10/01/2009

Labeler - A-S Medication Solutions (830016429)

ANDA077829

ANDA

Establishment			
Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-1089), REPACK(50090-1089)

Revised: 1/2020 A-S Medication Solutions