CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Ipca Laboratories Limited

Cetirizine Hydrochloride Tablets 10 mg

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 breat-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 yearsand 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

povidone, lactose monohydrate, corn starch, magnesium stearate, hypromelloses, titanium dioxide, polyethylene glycol, talc.

Questions?

call **1-800-406-7984**

Manufactured for:

Ohm Laboratories Inc.

14 Terminal Road

New Brunswick, NJ 08901

Manufactured by:

Ipca Laboratories Limited

1, Pharma Zone, SEZ Indore,

Pithampur 454775, (M.P.), India

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ohm Laboratories Inc.\Ranbaxy Group Company

NDC: 57451-5067-1

Cetirizine Hydrochloride Tablets 10 mg

1x 10000 Tablets

Each tablet contains:

Cetirizine hydrochloride 10 mg

Store between 20° to 25°C (68° to 77°F)

Code : MP/DRUGS/25/1/2008

Batch No. :

Mfg. Dt. :

Exp. Dt. :

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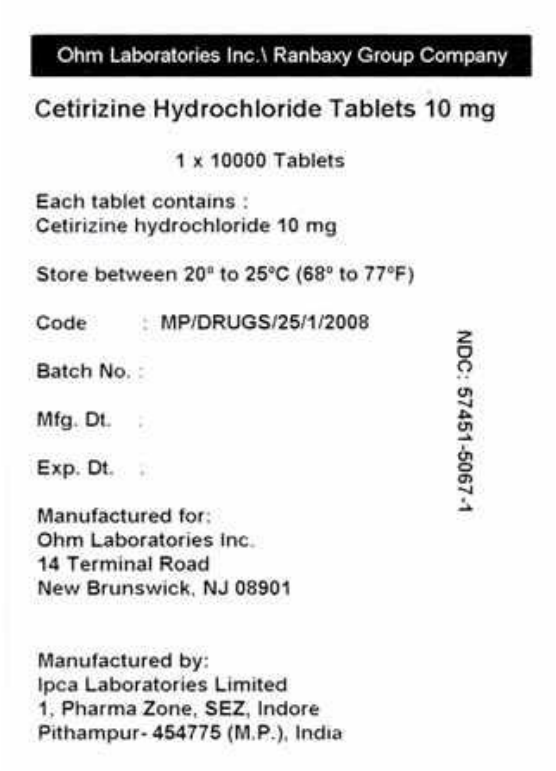

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57451-5067
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
POVIDONE K30 (UNII: U725QWY32X)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND (rectangular)	**Size**	9mm
Flavor		**Imprint Code**	RI52
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57451-5067-1	10000 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077498	12/27/2007	

Labeler - Ipca Laboratories Limited (862179827)

Registrant - Ipca Laboratories Limited (650387009)

Establishment

Name	Address	ID/FEI	Business Operations
Ipca Laboratories Limited		677600550	Manufacture

Revised: 3/2011 Ipca Laboratories Limited