# CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet Rebel Distributors Corp

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#### **Cetirizine Drug Facts**

## **Active ingredient**

(in each tablet)

Cetirizine HCl 10 mg

## Purpose

Antihistamine

#### Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

#### 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 reactions 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.

#### **Directions**

adults and children 6	One 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours.
years and over	A 5 mg product may be appropriate for less severe symptoms.

adults 65 years and	ask a doctor
over	
children under 6	ask a doctor
years of age	
consumers with liver	ask a doctor
or kidney disease	

#### Other information

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

## **Inactive ingredients**

Corn starch, hypromellose, lactose monohydrate, macrogol, magnesium stearate, povidone and titanium dioxide.

**Questions?** 1-800-525-8747

Manufactured in India by Sandoz Private Ltd.,

for Sandoz Inc., Princeton, NJ 08540

Rev.02/2008

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

## **Principal Display Panel**

NDC 21695-709-10 Bottle of 10

NDC 21695-709-14 Bottle of 14

NDC 21695-709-20 Bottle of 20

NDC 21695-709-30 Bottle of 30

**Cetirizine HCl Tablets** 

10 mg

antihis tamine

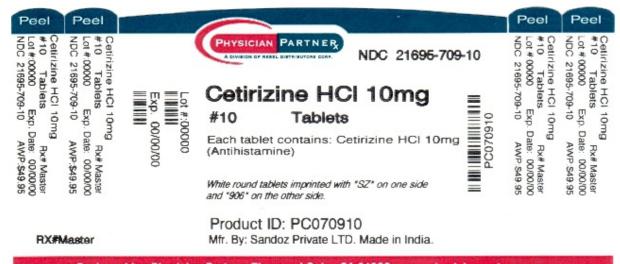
Do not use if individual blister unit is open or torn

**ALLERGY** 

Indoor & Outdoor Allergies

#### 24 hour Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose



Packaged by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com Store at controlled room temperature 15°-30° C (59°-86°F) Keep medication out of the reach of children.

## **CETIRIZINE HYDROCHLORIDE**

cetirizine hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-709(NDC:0781-1684)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CETIRIZINE HYDRO CHLO RIDE (UNII: 640047KTOA) (CETIRIZINE - UNII: YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg		

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
LACTO SE MO NO HYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6130)		
PO VIDO NE (UNII: FZ989 GH94E)		

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	WHITE (white to off-white)	Score	no score
Shape	ROUND (round shape)	Size	8 mm
Flavor		Imprint Code	SZ;906
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:21695-709-14	14 in 1 BOTTLE			
2	NDC:21695-709-20	20 in 1 BOTTLE			
3	NDC:21695-709-30	30 in 1 BOTTLE			
4	NDC:21695-709-10	10 in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077946	12/27/2007	

## **Labeler -** Rebel Distributors Corp (118802834)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rebel Distributors Corp		118802834	RELABEL, REPACK	

Revised: 2/2011 Rebel Distributors Corp