# CETIRIZINE HYDROCHLORIDE- cetirizine tablet Shopko Stores Operating Co., LLC

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**Drug Facts** 

## **ACTIVE INGREDIENT (IN EACH TABLET)**

Cetirizine HCl, USP 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 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

over

ask a doctor

children under 6 years of age

ask a doctor

consumers with liver or kidney disease

ask a doctor

#### OTHER INFORMATION

- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.
- store between 20° to 25° C (68° to 77° F)

#### **INACTIVE INGREDIENTS**

Corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide

#### **QUESTIONS?**

Call **1-800-406-7984** 

### PRINCIPAL DISPLAY PANEL

**SHOPKO**<sup>®</sup>

<sup>†</sup>Compare to the Active Ingredient of Zyrtec®

**Original Prescription Strength** 

Allergy Relief

Cetirizine HCl Tablets, 10 mg

Antihis tamine

**Indoor & Outdoor Allergies** 

24 Hour Relief of:

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

30 Tablets 10 mg Each

Manufacturedby: Ohm Laboratories Inc.

5093681/R0212



cetirizine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-939
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	
STARCH, CORN (UNII: O8232NY3SJ)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989GH94E)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	white	Score	no score
Shape	RECTANGLE (Rounded Off)	Size	9mm
Flavor		Imprint Code	R152
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-939-14	14 in 1 BLISTER PACK		
2	NDC:37012-939-30	30 in 1 BOTTLE		
3	NDC:37012-939-05	75 in 1 BOTTLE		

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

## Labeler - Shopko Stores Operating Co., LLC (023252638)

## Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Ohm Laboratories Inc.		184769029	manufacture(37012-939)	

Revised: 2/2013 Shopko Stores Operating Co., LLC