# CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet WinCo Foods, 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 years and 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

- \* TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING (for blister cartons only)
- 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?**

or to report an adverse event call 800-824-1706 Monday - Friday 9am - 4pm MST

KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION. See end panel for expiration date.

#### **DISTRIBUTED BY:**

WINCO FOODS, LLC, BOISE, ID 83704 5113308/0914

#### PRINCIPAL DISPLAY PANEL

Compare to the active ingredient of ZYRTEC®

#### WinCo FOODS

24 Hour

#### **Allergy Relief**

Indoor & Outdoor Allergies

Original Prescription Strength

Relief of:

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

# CETIRIZINE HCL TABLETS, USP 10 mg/ANTIHISTAMINE 14 Tablets



# **CETIRIZINE HYDROCHLORIDE**

cetirizine hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-247	
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	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
STARCH, CORN (UNII: O8232NY3SJ)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
PO VIDO NES (UNII: FZ989GH94E)		

Product Characteristics			
Color	white	Score	no score
Shape	RECTANGLE (rounded-off)	Size	9 mm
Flavor		Imprint Code	RI52
Contains			

l	Packaging				
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ı	1 NDC:67091-247-14	14 in 1 CARTON	0 1/0 8/20 15		
	1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077498	01/20/2012	

# Labeler - WinCo Foods, LLC (056098817)

# Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories Inc.		184769029	MANUFACTURE(67091-247)	

Revised: 12/2014 WinCo Foods, LLC