

## **CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet**

**Kinray**

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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

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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

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## OTHER INFORMATION

- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**
- 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

**Preferred Plus *Pharmacy***<sup>®</sup>

**NDC 61715-062-14**

**\*Compare to the Active Ingredient in Zyrtec**<sup>®</sup>

**Original Prescription Strength**

***ALL DAY ALLERGY***

***Cetirizine HCl Tablets, USP 10 mg***

**Antihistamine**

**Indoor & Outdoor Allergies**

**24 HOUR RELIEF OF:**

✓ **Sneezing**

✓ **Itchy, Watery Eyes**

✓ **Runny Nose**

✓ **Itchy Throat or Nose**

**14 Tablets 10 mg Each**

**Distributed By: Kinray, Inc.**

**5103484/R0613**

Keep the carton. It contains important information. See end panel for expiration date.

<p><b>Drug Facts</b> (continued)</p> <p><b>Drug Facts</b> (continued)</p> <p><b>Directions</b></p> <p>adults 65 years and over ask a doctor</p> <p>children under 6 years of age ask a doctor</p> <p>consumers with liver or kidney disease ask a doctor</p>	
<p><b>Warnings</b></p> <p>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, triprolidine, or sedatives.</p> <p>Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.</p> <p>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</p>	
<p><b>Uses</b></p> <p>temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> <li>sneezing</li> <li>runny nose</li> <li>itchy, watery eyes</li> <li>itching or the nose or throat</li> </ul>	
<p><b>Active Ingredient</b> (in each tablet) Cetirizine HCl USP 10 mg.....Antihistamine</p> <p><b>Purpose</b></p> <p>If pregnant or breast-feeding: not recommended</p> <p>If pregnant: ask a health professional before use.</p> <p>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).</p>	
<p><b>Other Information</b></p> <p>TAMPER EVIDENT: DO NOT USE IF BULSTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.</p> <p>store between 20° to 25° C (68° to 77° F)</p> <p><b>Inactive Ingredients</b></p> <p>corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide</p>	
<p><b>Questions?</b> call 1-800-406-7984</p>	



Preferred plus Pharmacy

Original Prescription Strength **ALL DAY ALLERGY**

Indoor & Outdoor Allergies

Cetirizine HCl Tablets, USP 10 mg Antihistamine

Preferred plus Pharmacy

Original Prescription Strength **ALL DAY ALLERGY**

\*Compare to the Active Ingredient in Zyrtec®

NDC 61715-062-14

**Cetirizine HCl Tablets, USP 10 mg**

Antihistamine

Indoor & Outdoor Allergies

**24 HOUR RELIEF OF:**

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

**14 Tablets 10 mg Each**

SATISFACTION GUARANTEED Preferred plus Pharmacy

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Distributed by: Kenvo Inc., Whitehouse, NJ 11987

All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

Manufactured by: Omni Laboratories Inc.

R0619

KIN 209-080

5 166093954

Expiration Date: \_\_\_\_\_

Batch No. \_\_\_\_\_

Non Varnish Area

Preferred plus Pharmacy

Original Prescription Strength **ALL DAY ALLERGY**

Indoor & Outdoor Allergies

**CETIRIZINE HYDROCHLORIDE**

cetirizine hydrochloride tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61715-062
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (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)	
POVIDONES (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE (Rounded-Off)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	R152
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-062-30	1 in 1 CARTON		
1		30 in 1 BOTTLE		
2	NDC:61715-062-90	1 in 1 CARTON		
2		90 in 1 BOTTLE		
3	NDC:61715-062-14	14 in 1 CARTON		
3		1 in 1 BLISTER PACK		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077498	12/07/2011	

**Labeler** - Kinray (012574513)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(61715-062)

Revised: 3/2014

Kinray