CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet Valu Merchandisers Company

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

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

INACTIVE INGREDIENTS

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

QUESTIONS?

Call 1-800-406-7984

PRINCIPAL DISPLAY PANEL

†COMPARE TO ACTIVE INGREDIENT OF ZYRTEC®

Best Choice® Brand

Original Prescription Strength

CETIRIZINE HCl TABLETS, 10 mg

Antihis tamine

Allergy

Indoor & Outdoor Allergies

24 Hour Relief of:

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

14 TABLETS

10 mg EACH

DISTRIBUTED BY: VALU MERCHANDISERS, CO.

5087936/0811

corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide Inactive ingredients

■ store between 20° to 25° C (68° to 77° F)

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

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ask a doctor	consumers with liver or kidney disease
ask a doctor	children under 6 years of age
ask a doctor	adults 65 years and over
one 10 mg tablet once dailly; do not take more than one 10 mg tablet in $\mathbb{Z}4$ hours. A $\mathbb{Z}4$ mg product may be appropriate for less severe symptoms.	adults and children 6 years and over

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); If pregnant or breast-feeding:

If breast-feeding: not recommended

If pregnant: ask a health professional before use.

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

- be careful when driving a motor vehicle or operating machinery
- drowsiness may occur avoid alcoholic drinks alcohol, sedatives, and tranquilizers may increase drowsiness
 - When using this product

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing Warnings

> ■ itching of the nose or throat ітсһу, watery еуеѕ

Drug Facts (continued)

Antihistamine Purpose

Active ingredient (in each tablet)
Cetirizine HCI, USP 10 mg.....







Original Prescription Strength

ABLETS, 10

Antihistamine

Allergy

Indoor & Outdoor Allergies

24 Hour Relief of:

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

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See end panel for expiration date.

Non Varnish Area

Batch No.

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Dro	duct	Info	rma	tion
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Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:63941-939Route of AdministrationORALDEA Schedule

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
CETIRIZINE HYDRO CHLO RIDE (CETIRIZINE)

CETIRIZINE HYDRO CHLO RIDE 10 mg

Inactive Ingredients Ingredient Name Strength STARCH, CORN HYPROMELLOSES LACTOSE MONOHYDRATE MAGNESIUM STEARATE POLYETHYLENE GLYCOLS POVIDONE TALC TITANIUM DIO XIDE

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:63941-939-54	14 in 1 BLISTER PACK		
2	NDC:63941-939-30	30 in 1 BOTTLE		
3	NDC:63941-939-60	60 in 1 BOTTLE		

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

Labeler - Valu Merchandisers Company (868703513)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories Inc.		184769029	manufacture(63941-939)	

Revised: 1/2013 Valu Merchandisers Company