CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Topco Associates LLC

Drug Facts

ACTIVE INGREDIENT (IN EACH CAPLET)

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.**
- 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 **1-888-423-0139**

PRINCIPAL DISPLAY PANEL

TopCare®

NDC 36800-244-18

ORIGINAL PRESCRIPTION STRENGTH

All Day Allergy

CETIRIZINE HCl TABLETS, 10 mg

ANTIHISTAMINE

24 Hour Relief of:

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

Indoor & Outdoor Allergies

5 TABLETS

10 mg EACH

COMPARE TO ZYRTEC®

active ingredient*

Distributed by: TOPCO ASSOCIATES LLC

5099010/1012

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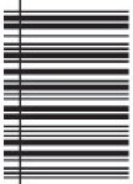
TopCare®

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007
1-888-423-0139 ©TOPCO OHM1012 topcare@topco.com

Batch No.

Expiration Date:

Non Varnish Area



This TOPCARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

TEAR ALONG PERFORATION, PEEL OFF PAPER AND PUSH PRODUCT THROUGH FOIL. IF DIFFICULT TO OPEN USE SCISSORS.

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Uses

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Inactive ingredients

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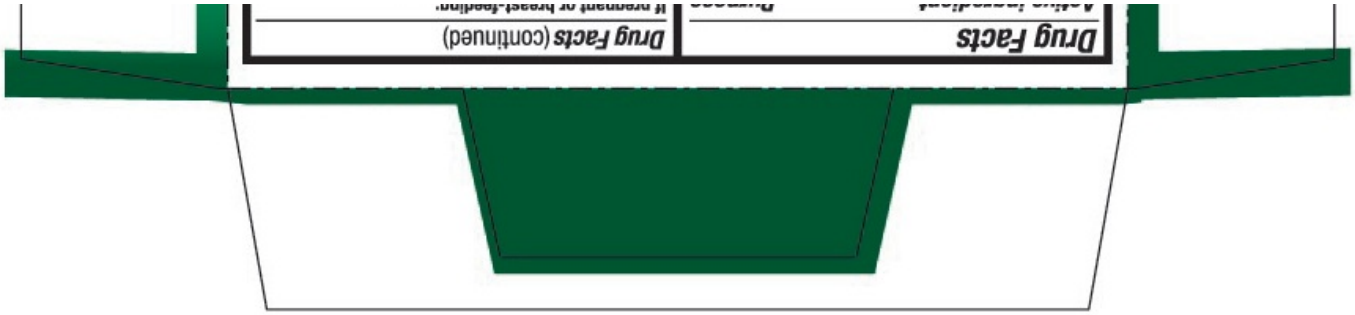
Drug Facts (continued)

Questions? call **1-888-423-0139**

*This product is not manufactured or distributed by McNeil-PPC, Inc., distributor of Zyrtec®. Zyrtec® is a registered trademark of UCB Pharma, S.A.

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



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-244
Route of Administration	ORAL	**DEA Schedule**	

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)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-244-18	5 in 1 BLISTER PACK		

Marketing Information

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

Labeler - Topco Associates LLC (006935977)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(36800-244)

Revised: 11/2012 Topco Associates LLC