

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Dispensing Solutions, Inc.

Drug Facts

Active ingredient

(in each tablet)

Cetirizine HCl 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 reactions 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.

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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

- Store between 20 to 25 C (68 to 77 F)




Inactive ingredients

Corn starch, hypromellose, lactose monohydrate, macrogol, magnesium stearate, povidone and titanium dioxide.

Questions? 1-800-525-8747

Manufactured in India by Sandoz Private Ltd.,

Principal Display Panel

<p>BULK SOURCE DATA MFD. FOR: SANDOZ INC. PRINCETON, NJ 08540</p> <p>PRODUCT ID: OFF WHITE ROUND FILM COATED TABLET DEBOSSED SZ / 906</p> <p>BULK SOURCE NDC: 00781-1684-01 MFR. LOT: XXXXXX PEDIGREE #: 20509309</p> <p>DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER</p> 	 CETIRIZINE HCl 10 mg XX TABLETS NDC 66336-0336-XX PRODUCT # 818-XX EACH TABLET CONTAINS: CETIRIZINE HYDROCHLORIDE 10 mg (PURPOSE: ANTIHISTAMINE) LOT# SAMPLE EXP: 00-00 Rx # 25089522	<p>WARNING: KEEP OUT OF CHILDREN'S REACH STORE BETWEEN 68° - 77° F. SEE USP.</p> <p>818- XX NDC 66336-0336- XX CETIRIZINE HCl 10 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00781-1684-01 RX# 25089522</p> <p>818- XX NDC 66336-0336- XX CETIRIZINE HCl 10 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00781-1684-01 RX# 25089522</p> <p>818- XX NDC 66336-0336- XX CETIRIZINE HCl 10 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00781-1684-01 RX# 25089522</p>  <p>Packaged Exclusively By: DISPENSING SOLUTIONS inc. Santa Ana, CA 92704</p>
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NDC 66336-0336-XX

NDC 66336-0336-14

Cetirizine HCl Tablets

10 mg

antihistamine

Tablets.

ALLERGY

Indoor and Outdoor Allergies

24 hour Relief of

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

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66336-336(NDC:0781-1684)
Route of Administration	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)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOLs (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	white (white to off-white)	Score	no score
Shape	ROUND (round shape)	Size	8mm
Flavor		Imprint Code	SZ;906
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66336-336-14	14 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077946	12/27/2007	

Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(66336-336) , repack(66336-336)

Revised: 9/2012

Dispensing Solutions, Inc.