CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet Sandoz Inc

Drug Facts

Active ingredient

(in each tablet)

Cetirizine HCl 5 mg

Purpose

Antihistamine

Keep Out of Reach of Children

In case of overdose, get medical help or contact a Poison Control Center right away.

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.

Directions

adults and children 6 years and over	1 to 2 tablets once daily; depending upon severity of symptoms; do not take more than 2 tablets in 24
	hours
adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in
	24 hours
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.,

for Sandoz Inc., Princeton, NJ 08540

Rev.06/2013

Principal Display Panel

NDC 0781-1683-64

Cetirizine HCl Tablets, USP

5 mg

antihis tamine

30 Tablets

Do not use if individual blister unit is open or torn

ALLERGY

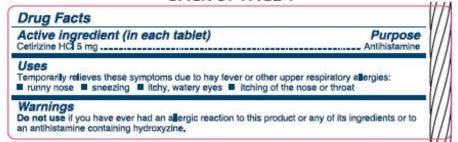
Indoor & Outdoor Allergies

24 hour Relief of

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



BACK OF PAGE 1



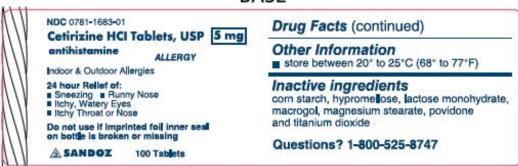
FRONT OF PAGE 2

	Drug Facts (continued)	
	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 ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ avoid alcoholic drinks ■ 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 awa	
	If pregnant or breast-feeding: ■ If pregnant: ask a health professional before use ■ If breast-feeding; not recommended	

BACK OF PAGE 2

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.		
Directions adults and children 6 years and over	1 to 2 tablets once daily; depending upon severity of symptoms; do not take more than 2 tablets in 24 hours	
adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours	
children under 6 years of age	ask a doctor	
	ask a doctor	

BASE



cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0781-1683
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CETIRIZINE HYDRO CHLO RIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII: YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)			
LACTO SE MO NO HYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			

Product Characteristics			
Color	WHITE (white to off-white)	Score	no score
Shape	ROUND (round shape)	Size	6 mm
Flavor		Imprint Code	SZ;905
Contains			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:0781-1683- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	
	2 NDC:0781-1683- 64	30 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	12/27/2007	

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

Revised: 6/2013 Sandoz Inc