CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Sandoz Inc

Drug Facts

Active ingredient

(in each tablet)

Cetirizine HCl 10 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	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 20º to 25º C (68º to 77º 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 0781-1684-64

Cetirizine HCl Tablets, USP

10 mg

antihistamine

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, Watery Eyes
- Itchy Throat or Nose

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Drug Facts

Active ingredient (in each tablet) — **Purpose**
Cetirizine HCl 10 mg ..... 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.

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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 away.

If pregnant or breast-feeding:
■ If pregnant: ask a health professional before use ■ If breast-feeding: not recommended

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Drug Facts (continued)

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	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

BASE

NDC 0781-1684-01
Cetirizine HCl Tablets, USP 10 mg
antihistamine
ALLERGY
Indoor & Outdoor Allergies
24 hour Relief of:
■ Sneezing ■ Runny Nose
■ Itchy, Watery Eyes
■ Itchy Throat or Nose
Do not use if imprinted foil inner seal on bottle is broken or missing
SANDOZ 100 Tablets

Drug Facts (continued)

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

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (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:0781-1684-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	
2	NDC:0781-1684-64	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	

Labeler - Sandoz Inc (005387188)

Revised: 6/2013 Sandoz Inc