**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet**
**Sandoz Inc**

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**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 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 0781-1683-64**

**Cetirizine HCl Tablets, USP**

**5 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, Water Eyes
- Itchy Throat or Nose


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## Drug Facts

**Active ingredient (in each tablet)** — **Purpose**

Cetirizine HCl 5 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 | 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 |

BASE

NDC 0781-1683-01
**Cetirizine HCl Tablets, USP 5 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:0781-1683 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **CETIRIZINE HYDROCHLORIDE** (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZINE HYDROCHLORIDE | 5 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** | 6mm |
| **Flavor** | | **Imprint Code** | SZ;905 |
| **Contains** | | | |

| 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 | |

**Labeler -** Sandoz Inc (005387188)