

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

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**Drug Facts**

**Active ingredient**

(in each chewable tablet)

Cetirizine HCl 10 mg

**Purpose**

Antihistamine

**Keep Out of Reach of Children**

**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**

- may be taken with or without water
- Chew or crush tablets completely before swallowing

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**

acesulfame potassium, artificial flavors, benzyl alcohol, betadex, colloidal silicon dioxide, dl-alpha-tocopherol, ferric oxide red, ferric oxide yellow, lactose monohydrate, magnesium stearate, maltodextrin, microcrystalline cellulose, propylene glycol, talc and tutti frutti flavor

**Questions?** 1-800-525-8747

Product of India

Manufactured by Sandoz Private Ltd.,

for Sandoz Inc., Princeton, NJ 08540

Rev.10/2024

**Principal Display Panel**

**NDC 0781-5284-64**

***Children's***

**Cetirizine HCl Chewable Tablets**

**10 mg**

**antihistamine**

**Tutti Frutti Flavored**

**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
- No Water needed  
Chew or crush tablets completely before swallowing

***6 yrs. and older 10 mg each***

NDC 0781-5284-64

# Children's Cetirizine HCl Chewable Tablets

**10 mg** antihistamine

Tutti Frutti Flavored

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**SANDOZ**



NDC 0781-5284-64  
**10 mg** antihistamine  
Tutti Frutti Flavored  
**SANDOZ**  
Children's  
**Cetirizine HCl Chewable Tablets**  
Code No.: MH0805SD-548

NDC 0781-5284-64

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**10 mg** antihistamine

Tutti Frutti Flavored

**SANDOZ**



90 25 150

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### Drug Facts (continued)

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**Questions?** 1-800-525-8747

Manufactured in India by Sandoz Private Ltd., for Sandoz Inc., Princeton, NJ 08540

Rev. 10/2024

46960443

## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:0781-5284

**Route of Administration**

ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>BETADEX</b> (UNII: JV039JZZ3A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

**Product Characteristics**

<b>Color</b>	YELLOW (peach, mottled)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	SZ;106
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0781-5284-64	30 in 1 CARTON	02/14/2008	
1	NDC:0781-5284-06	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078692	02/14/2008	

**Labeler** - Sandoz Inc (005387188)

