

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, chewable
Sandoz Inc

Drug Facts

Active ingredient

(in each chewable tablet)

Cetirizine HCl 5 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

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

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

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

Rev.06/2014

Principal Display Panel

NDC 0781-5283-64

Children's

Cetirizine HCl Chewable Tablets

5 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

6 yrs. and older 5 mg each



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0781-5283
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BETADEX (UNII: JV039JZZ3A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	YELLOW (peach, mottled)	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	SZ;104
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0781-5283-64	30 in 1 CARTON	02/14/2008	
1	NDC:0781-5283-06	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)

Revised: 6/2014

Sandoz Inc