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-alphatocopherol, 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

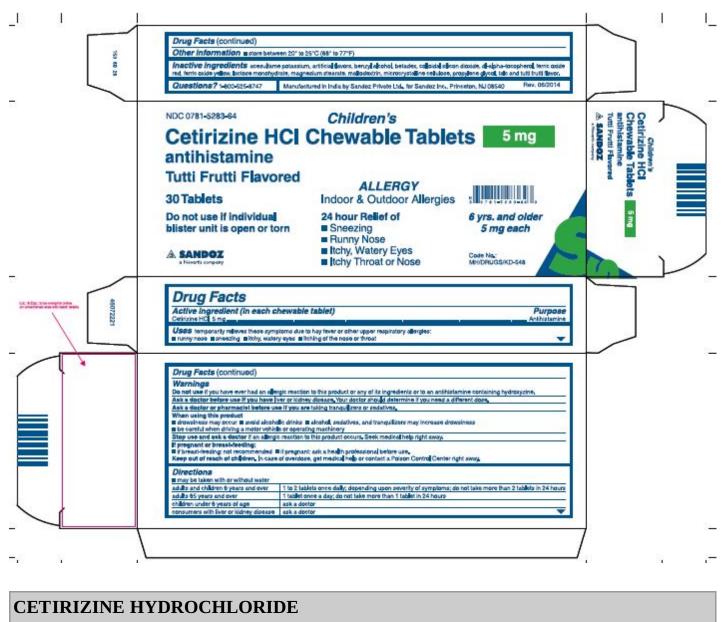
Rev.06/2014

Principal Display Panel NDC 0781-5283-64 *Children's* Cetirizine HCl Chewable Tablets 5 mg antihis tamine 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 tablet, chewable

| Product Information | | | | | | | | |
|---|-----------------------------|--------------------------|----------------------------|---------------|------|--|--|--|
| Product T ype | HUMAN OTC DRUG | Item Code (Source) | | NDC:0781-5283 | | | | |
| Route of Administration | ORAL | | | | | | | |
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| Active Ingredient/Active Moiety | | | | | | | | |
| Ingredient Name | | Basis of Strength | | Strength | | | | |
| CETIRIZINE HYDRO CHLO RIDE (UNI UNII: YO7261ME24) | : 640047KTOA) (CETIRIZINE - | | CETIRIZINE HYDROCHLORIE | DE | 5 mg | | | |
| | | | | | | | | |

| NDC:0781-5283-64 30 in 1 CARTON 02/14/20 NDC:0781-5283-06 1 in 1 BLISTER PACK; Type 0: Not a Combination Product Marketing Information | | | | | |
|--|-------------------|--------------------|--|--|--|
| CESULFAME POTASSIUM (UNII: 230V73Q5G9) ENZYL ALCOHOL (UNII: LKG8494WBH) ETADEX (UNII: JV039JZZ3A) ILICON DIO XIDE (UNII: ETJ7Z6 XBU4) LIPHATO COPHER L ACETATE, DL - (UNII: WRIWPI7EW8) ERRIC O XIDE RED (UNII: 1K09F3G675) ERRIC O XIDE YELL U W (UNII: EX438 02MRT) ACTOSE MONOHYDRATE (UNII: 2007706130) ALTODEXTRIN (UNII: 7CVR7L4A2D) ICRO CRYSTALLINE CELLULOSE (UNII: 0P1R32D61U) ROPYLENE GLYCOL (UNII: 6DC9Q167V3) ALC (UNII: 7SEV7J4RIU) FODUCT Characteristics olor YELLOW (peach, motuled) Score hape ROUND Size avor ROUND Size Imprint Contains I CARTON 02/14/20 NDC:0781-5283-06 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | Strength | | | |
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Labeler - Sandoz Inc (005387188)

Revised: 6/2014

Sandoz Inc