

CHILDRENS ZYRTEC- cetirizine hydrochloride tablet, chewable

A-S Medication Solutions

CHILDRENS ZYRTEC

Drug Facts

Active ingredient (in each chewable tablet)

Cetirizine HCl 10 mg

Purpose

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.

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. (1-800-222-1222)

Directions

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

adults and children 6 years and over	Chew and swallow 1 tablet (10 mg) once daily; do not take more than 1 tablet (10 mg) 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)
- **do not use if blister unit is torn or broken**

Inactive ingredients

betadex, corn starch, flavor, lactose monohydrate, magnesium stearate, mannitol, silicified microcrystalline cellulose, sucralose

Questions?

call **1-800-343-7805** (toll-free) or **215-273-8755** (collect)

HOW SUPPLIED

Product: 50090-6781

NDC: 50090-6781-0 6 TABLET, CHEWABLE in a BLISTER PACK / 4 in a CARTON

cetirizine hydrochloride



CHILDRENS ZYRTEC

cetirizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-6781(NDC:50580-791)
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
BETADEX (UNII: JV039JZZ3A)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor	GRAPE	Imprint Code	CTZ;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:50090-6781-0	4 in 1 CARTON	10/26/2023	
1		6 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
NDA	NDA021621	06/21/2021	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-6781)

Revised: 11/2023

A-S Medication Solutions