ZYRTEC- cetirizine hydrochloride tablet, chewable Johnson & Johnson Consumer Inc.

Zyrtec Allergy

Drug Facts

Active ingredient (in each 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

Directions

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

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, lactose monohydrate, magnesium stearate, mannitol, silicified microcrystalline cellulose, sucralose

Questions?

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

PRINCIPAL DISPLAY PANEL

Original Prescription Strength NDC 50580-753-24

ZYRTEC ®

Cetirizine HCl Chewable tablets, 10 mg /antihistamine

ALLERGY

Indoor + Outdoor

Allergies

Chewables

DYE-Free

24 HOUR

Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

Actual

Size

No Water

Needed

Chew or crush tablets completely

before swallowing

24 Chewable Tablets

10 mg each



cetirizine hydrochloride tablet, chewable

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HUMAN OTC DRUG NDC:50580-753 **Product Type Item Code (Source)**

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE -**CETIRIZ INE** 10 mg

UNII:YO7261ME24)

HYDROCHLORIDE

Inactive Ingredients			
Ingredient Name	Strength		
BETADEX (UNII: JV039JZZ3A)			
STARCH, CORN (UNII: 08232NY3SJ)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MANNITOL (UNII: 3OWL53L36A)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	CET;10
Contains			

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:50580-753- 24	4 in 1 CARTON	06/20/2022				
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	06/20/2022	