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

Children's Zyrtec Chewable Tablets 10mg

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	ack a doctor
years and over	ask a doctor
children	
under 6	ask a doctor
years of age	
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)

PRINCIPAL DISPLAY PANEL

Original Prescription Strength

NDC 50580-791-01

Children's

ZYRTEC ®

Cetirizine HCl chewable tablets,

10 mg/antihistamine

ALLERGY

INDOOR + OUTDOOR ALLERGIES

Dye-Free Chewables

24 HOUR RELIEF OF

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

6yrs. & older Grape Flavor

Actual Size

Chew or crush tablets completely before swallowing

10 mg 24 Chewable Tablets



CHILDRENS ZYRTEC

cetirizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-791
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE 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: 30WL53L36A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50580- 791-01	4 in 1 CARTON	06/21/2021		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:50580- 791-03	1 in 1 CARTON	09/01/2022		
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product			
3	NDC:50580- 791-02	8 in 1 CARTON	01/01/2023		
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product			
4	NDC:50580- 791-72	3 in 1 CARTON	01/15/2024		
4		24 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 - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024 Johnson & Johnson Consumer Inc.