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

Children's Zyrtec Chewable Tablets 2.5mg

Drug Facts

Active ingredient (in each chewable tablet)

Cetirizine HCl 2.5 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

children 2 to under 6 years of age	Chew and swallow 1 tablet (2.5 mg) once daily; If needed, dose can be increased to a maximum of 2 tablets (5 mg) once daily or 1 tablet (2.5 mg) every 12 hours. Do not give more than 2 tablets (5 mg) in 24 hours.
adults and children 6 years and over	Chew and swallow 2 tablets (5 mg) or 4 tablets (10 mg) once daily depending upon severity of symptoms; do not take more than 4 tablets (10 mg) in 24 hours.
adults 65 years and over	Chew and swallow 2 tablets (5 mg) once daily; do not take more than 2 tablets (5 mg) in 24 hours.
children under 2 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)

PRINCIPAL DISPLAY PANEL

NDC 50580-790-01

Children's

ZYRTEC ®

Cetirizine HCl chewable tablets,

2.5 mg/antihistamine

ALLERGY

INDOOR + OUTDOOR

ALLERGIES

Dye-Free

Chewables

24

HOUR

RELIEF OF

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

2 yrs.

& older

Grape Flavor

Actual

Size

2.5 mg

12 Chewable Tablets

Chew or crush tablets completely

before swallowing

CHILDRENS ZYRTEC

cetirizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-790
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	2.5 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**	8mm
Flavor	GRAPE	**Imprint Code**	CTZ
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-790-01	2 in 1 CARTON	06/21/2021	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-790-02	4 in 1 CARTON	06/21/2021	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-790-03	1 in 1 CARTON	09/01/2022	
3		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 - Johnson & Johnson Consumer Inc. (878046358)

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