ZYRTEC ALLERGY- cetirizine hydrochloride tablet, orally disintegrating 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 Poison Control Center right away. (1-800-222-1222)

Directions

Tablet melts in mouth. Can be taken with or without water.

adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet 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). Avoid high humidity.
- do not use if blister unit is torn or broken

Inactive ingredients

amino methacrylate copolymer, anhydrous citric acid, colloidal silicon dioxide, crospovidone, flavors, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, sodium bicarbonate, sodium starch glycolate, sucralose

Questions?

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

PRINCIPAL DISPLAY PANEL

Original Prescription Strength

NDC 50580-778-24

ZYRTEC ®

Cetirizine HCI orally disintegrating tablets 10mg/antihistamine

ALLERGY

INDOOR + OUTDOOR ALLERGIES

Dissolve Tabs

24 HOUR RELIEF OF

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

Melts In Your Mouth CITRUS FLAVOR

Actual Size

24

ORALLY DISINTEGRATING TABLETS

10 mg each



ZYRTEC ALLERGY

cetirizine hydrochloride tablet, orally disintegrating

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50580-778

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	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSPOVIDONE (UNII: 2S7830E561)		
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MANNITOL (UNII: 3OWL53L36A)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Product Characteristics			
Color	white (White to Off-white)	Score	no score
Shape	ROUND	Size	10mm
Flavor	CITRUS (citrus-ice)	Imprint Code	Z10
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-778- 12	2 in 1 CARTON	01/20/2014	04/30/2017
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-778- 24	4 in 1 CARTON	01/20/2014	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-778- 66	11 in 1 CARTON	01/20/2014	03/31/2017

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	NDA022578	01/20/2014	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 5/2023 Johnson & Johnson Consumer Inc.