ZYRTEC ALLERGY- cetirizine hydrochloride tablet, film coated Kenvue Brands LLC

Zyrtec Allergy

Drug Facts

Active ingredient (in each tablet)

Cetirizine HCl 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:

 \blacksquare if breast-feeding: not recommended \blacksquare 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

adults and children 6 years and over

1 tablet (5 mg) or 2 tablets (10 mg) once daily depending

upon severity

of symptoms; do not take more than 2 tablets (10mg) in 24

hours.

adults 65 years and

over

1 tablet (5 mg) once daily; do not take more than 1 tablet (5

mg) in 24 hours.

children under 6 years

of age

ask a doctor

consumers with liver

kidney disease

ask a doctor

Other information

■ store between 20° to 25°C (68° to 77°F)

■ do not use if carton is opened. do not use if pouch is torn or damaged

■ meets USP Dissolution Test 2

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-754-15

Zyrtec®

ALLERGY

Cetirizine HCI Tablets **5mg**/antihistamine

24 Hour relief of Sneezing

Runny Nose

Itchy Throat or Nose

Itchy, Watery Eyes

15 Tablets 5 mg each

Actual Size

Take 1 to 2 tablets* once daily depending on the severity of your symptoms *Adults 65 and older take only one tablet per day

Indoor & Outdoor Allergies

5mg Strength Tablets

15 Tablets 5 mg each





ZYRTEC ALLERGY

cetirizine hydrochloride tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-754	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
	CETIRIZ INE HYDROCHLORIDE	5 mg		

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	white	Score	no score
Shape	RECTANGLE	Size	8mm
Flavor		Imprint Code	Z;5MG
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50580-754- 35	1 in 1 CARTON	02/15/2025		
1		35 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:50580-754- 15	15 in 1 CARTON	02/15/2025		
2		1 in 1 POUCH; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019835	02/15/2025	

Labeler - Kenvue Brands LLC (118772437)

Revised: 1/2025 Kenvue Brands LLC