ZYRTEC 1S BLISTER- cetirizine hydrochloride tablet, film coated JC World Bell Wholesale Co., Inc.

Zyrtec 1s Blister, 1 Tablet per Blister, 6 Blisters per Box

Drug Facts

Active ingredient ((in each tablet))

Cetrizine 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 kidny 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 reastion 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

adults and children 6 years and over	one 10mg tablet once daily; do not take more than one 10mg tabelt 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 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)

Package Labeling:













FRONT CARD





ZYRTEC 1S BLISTER

cetirizine hydrochloride tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50269-014(NDC:50580-726)	
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		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics				
Color	white	Score	2 pieces	
Shape	RECTANGLE	Size	9mm	
Flavor		Imprint Code	ZYRTEC;10;MG	
Contains				

F	Packaging						
#	tem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:50269-014- 01	6 in 1 BOX	01/20/2019				
1		1 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	NDA019835	01/20/2019		

Labeler - JC World Bell Wholesale Co., Inc. (805257581)

Establishment				
Name	Address	ID/FEI	Business Operations	
JC World Bell Wholesale Co., Inc.		805257581	repack(50269-014)	

Establishment			
Name	Address	ID/FEI	Business Operations

Kenvue Brands LLC 878046358 manufacture(50269-014)

Revised: 12/2024 JC World Bell Wholesale Co., Inc.