

**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))

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

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

Original Prescription Strength

ZYRTEC

Cetirizine HCl tablets
10 mg /antihistamine

ALLERGY

24 hour Indoor & Outdoor Allergies
Relief of Sneezing • Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

GO PACKS
1 Portable Pouch
1 tablet per pouch



Original Prescription Strength

ZYRTEC

Cetirizine HCl tablets
10 mg /antihistamine

ALLERGY

24 hour Indoor & Outdoor Allergies
Relief of Sneezing • Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

GO PACKS
1 Portable Pouch
1 tablet per pouch

Original Prescription Strength

ZYRTEC

Cetirizine HCl tablets
10 mg /antihistamine

ALLERGY

24 hour Indoor & Outdoor Allergies
Relief of Sneezing • Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

GO PACKS
1 Portable Pouch
1 tablet per pouch

Original Prescription Strength

ZYRTEC

Cetirizine HCl tablets
10 mg /antihistamine

ALLERGY

24 hour Indoor & Outdoor Allergies
Relief of Sneezing • Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

GO PACKS
1 Portable Pouch
1 tablet per pouch

Original Prescription Strength

ZYRTEC

Cetirizine HCl tablets
10 mg /antihistamine

ALLERGY

24 hour Indoor & Outdoor Allergies
Relief of Sneezing • Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

GO PACKS
1 Portable Pouch
1 tablet per pouch

Drug Facts	Purpose
Active ingredient (in each tablet) Cetirizine HCl 10 mg	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: • 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 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 • do not use if pouch is torn or damaged • meets USP Dissolution Test 2	store between 20° to 25°C (68° to 77°F)
Inactive ingredients calcium silicate dihydrate, croscarmellose sodium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide	
Questions? call 1-800-343-7805 (toll-free) or 215-273-8705 (collect)	
Active ingredient made in Switzerland Distributed by: AMERSON & JOHNSON CONSUMER INC. Medical Consumer Health Care Division, Fort Washington, PA 19004 USA GABLJ72017 www.zyrtec.com USD 001 972 USD 004 806 USD 005 056 USD 7 808 475 The trade dress of the ZYRTEC package is subject to trademark protection. Product is manufactured and distributed with permission of Manufacturer by J.C. Wargo/All Whitecaps Co., Inc. 275-283 The Wood Ave., Rockersburg, NJ, 07001 Office #1-800-468-1099	LOT: EXP: 8 52682 50394 6

ZYRTEC

GO PACKS
1 Portable Pouch
1 tablet per pouch

NO PRINT

FRONT CARD

Original Prescription Strength

ZYRTEC

Cetirizine HCl tablets
10 mg /antihistamine

ALLERGY

24 hour Indoor & Outdoor Allergies
Relief of Sneezing • Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose



Drug Facts	Purpose
Active ingredient (in each tablet) Cetirizine HCl 10 mg	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: • 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 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 • do not use if pouch is torn or damaged • meets USP Dissolution Test 2	store between 20° to 25°C (68° to 77°F)
Inactive ingredients calcium silicate dihydrate, croscarmellose sodium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide	
Questions? call 1-800-343-7805 (toll-free) or 215-273-8705 (collect)	
Active ingredient made in Switzerland Distributed by: AMERSON & JOHNSON CONSUMER INC. Medical Consumer Health Care Division, Fort Washington, PA 19004 USA GABLJ72017 www.zyrtec.com USD 001 972 USD 004 806 USD 005 056 USD 7 808 475 The trade dress of the ZYRTEC package is subject to trademark protection. Product is manufactured and distributed with permission of Manufacturer by J.C. Wargo/All Whitecaps Co., Inc. 275-283 The Wood Ave., Rockersburg, NJ, 07001 Office #1-800-468-1099	LOT: EXP: 8 52682 50394 6

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: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
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			

Packaging				
#	Item 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

Name	Address	ID/FEI	Operations
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division		878046358	manufacture(50269-014)

Revised: 4/2022

JC World Bell Wholesale Co., Inc.