

ZYRTEC- cetirizine hydrochloride capsule, liquid filled
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

ZYRTEC

Drug Facts

Active ingredient (in each capsule)

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 10 mg capsule once daily; do not take more than one 10 mg capsule in 24 hours. A 5 mg product may be
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	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 at 20°-25°C (68°-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- protect from light
- **do not use if foil inner seal printed with "SAFETY SEAL®" is broken or missing**

Inactive ingredients

gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol 400, purified water, sodium hydroxide, sorbitan, sorbitol

Questions?

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

PRINCIPAL DISPLAY PANEL

Original Prescription Strength

NDC 50580-779-12

**ZYRTEC®
ALLERGY**

**INDOOR + OUTDOOR
ALLERGIES**

**Cetirizine HCl/
antihistamine
10 mg capsules**

**LIQUID
GELS**

**24
HOUR
RELIEF OF**

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

(Actual Size)

**12
LIQUID GELS*
*LIQUID-FILLED CAPSULES
10 mg each**

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ZYRTEC®

Cetirizine HCl/
antihistamine
10 mg capsules

ALLERGY

Drug Facts (continued)

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Inactive ingredients also listed on panel 2





3 0045-0204-318

The trade dress of this ZYRTEC® package is subject to trademark protection.

inactive ingredients: gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol 400, purified water, sodium hydroxide, sorbitan, sorbitol

Questions? call 1-800-343-7905 (toll-free) or 215-273-8755 (collect)

Active ingredient made in Israel

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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ZYRTEC

cetirizine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-779
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
gelatin, unspecified (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
mannitol (UNII: 3OWL53L36A)	
polyethylene glycol 400 (UNII: B697894SGQ)	
water (UNII: 059QF0K00R)	
sodium hydroxide (UNII: 55X04QC32I)	
sorbitan (UNII: 6O92ICV9RU)	
sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color	YELLOW (Clear)	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	Z10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:50580-779			

1	NDC:50580-779-12	1 in 1 PACKAGE	02/08/2010	
1		12 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-779-25	1 in 1 PACKAGE	02/08/2010	
2		25 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:50580-779-40	1 in 1 PACKAGE	02/08/2010	
3		40 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:50580-779-65	65 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	02/08/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022429	02/08/2010	

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 4/2017

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division