

ZYRTEC ALLERGY- cetirizine hydrochloride capsule, liquid filled
Kenvue Brands LLC

ZYRTEC Allergy

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

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 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°-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 imprinted with "Sealed For Your Safety" is broken or missing**

Inactive ingredients

butylated hydroxytoluene, gelatin, glycerin, 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 50580-786-13

ZYRTEC®

ALLERGY

Cetirizine HCl capsules

10 mg/antihistamine

Indoor &

Outdoor

Allergies

Strength

10 mg Capsules

LIQUID GELS*

24 Hour relief of

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

12 Liquid-Filled Capsules

10 mg each

Dye-Free

Actual Size

12 *LIQUID-FILLED

CAPSULES



12

Liquid-Filled Capsules
10 mg each

✓ Dye-Free



Actual Size

12 *LIQUID-FILLED CAPSULES

Active ingredient made in India.

Distributed by: **KENVUE BRANDS LLC** Summit, NJ 07901
Pat. www.kenvuepats.com
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zyrtec.com



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Antihistamine

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Warnings
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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 ■ avoid alcoholic drinks ■ drowsiness may occur ■ 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.

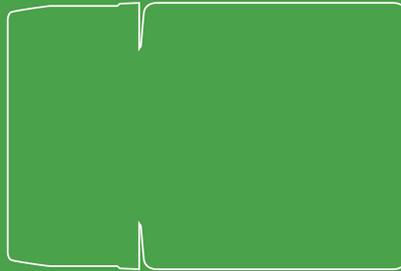
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Important: Read all product information before using. Keep this box for important information.



Actual Size

ZYRTEC ALLERGY

cetirizine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-786
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
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GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9DOZ171K)	

Product Characteristics

Color	white (Clear)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	CZ10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-786-12	1 in 1 PACKAGE	04/15/2024	
1		12 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-786-25	1 in 1 PACKAGE	04/15/2024	
2		25 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:50580-786-40	1 in 1 PACKAGE	04/15/2024	
3		40 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:50580-786-65	65 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	04/15/2024	
5	NDC:50580-786-13	1 in 1 CARTON	12/01/2024	
5		12 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:50580-786-26	1 in 1 CARTON	12/01/2024	
6		25 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:50580-786-41	1 in 1 CARTON	12/01/2024	
7		40 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:50580-786-66	65 in 1 PACKAGE; Type 0: Not a Combination Product	12/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213105	04/15/2024	

