

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

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**Zyrtec<sup>®</sup> Allergy**

***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 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

- store between 20° to 25°C (68° to 77°F)
- **do not use if foil inner seal imprinted with “Sealed For Your Safety” is broken or missing**
- 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

### Original Prescription Strength

NDC 50580-726-71

**ZYRTEC<sup>®</sup>**  
**ALLERGY**

**Cetirizine HCl tablets**  
**10 mg /antihistamine**

### Indoor & Outdoor Allergies

Strength 10mg Tablets

## 24 hour

Relief of

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

**30** Tablets  
10 mg each

Actual Size



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

**Drug Facts (continued)**  
**Active ingredient (in each tablet)** Cetirizine HCl 10mg  
**Purpose** Antihistamine

**Uses** Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
 ■ runny nose ■ sneezing ■ 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**  
 ■ avoid alcoholic drinks  
 ■ drowsiness may occur  
 ■ alcohol, sedatives, and tranquilizers may increase drowsiness

**Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.**  
 ■ Be careful when driving a motor vehicle or operating machinery

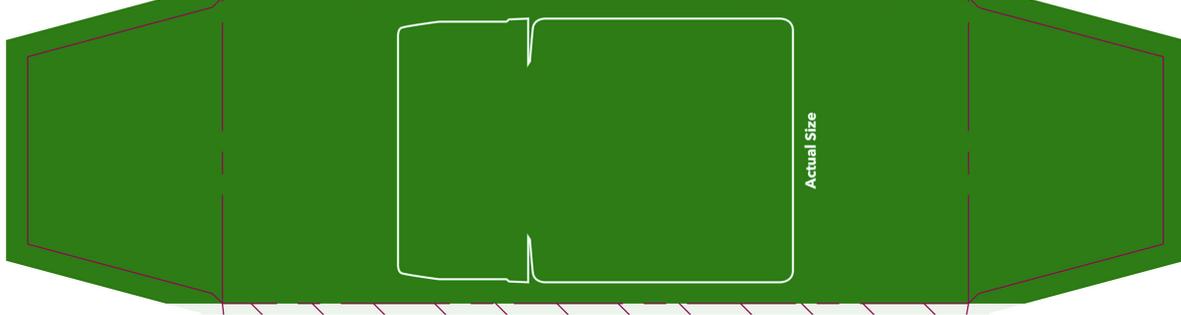
**If pregnant or breastfeeding:** ■ If breastfeeding, not recommended

**Other information**  
 ■ do not use if foil inner seal imprinted with "Sealed for Your Safety" is broken or missing  
 ■ store between 20° to 25° C (68° to 77° F)  
 ■ meets USP Dissolution Test 2

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

**Directions**  
 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

**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)

# ZYRTEC ALLERGY

cetirizine hydrochloride tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-726
<b>Route of Administration</b>	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)	
CROSCARMELOSE 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

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	RECTANGLE (rounded-off rectangular biconvex tablet)	<b>Size</b>	9mm

Flavor		Imprint Code		ZYRTEC;10;MG
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-726-03	50 in 1 CARTON	01/01/2008	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-726-13	3 in 1 CARTON	03/21/2009	01/31/2021
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-726-30	5 in 1 PACKAGE	01/01/2008	11/30/2022
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:50580-726-32	14 in 1 PACKAGE	01/01/2008	11/30/2022
4		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:50580-726-36	1 in 1 PACKAGE	01/01/2008	
5		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:50580-726-50	1 in 1 PACKAGE	01/26/2010	
6		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:50580-726-51	2 in 1 PACKAGE	01/26/2010	11/30/2022
7		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:50580-726-38	1 in 1 PACKAGE	01/01/2008	12/31/2022
8		45 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
9	NDC:50580-726-70	1 in 1 PACKAGE	01/01/2008	
9		70 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
10	NDC:50580-726-90	2 in 1 PACKAGE	01/26/2010	
10		45 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
11	NDC:50580-726-66	75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/01/2008	
12	NDC:50580-726-40	1 in 1 PACKAGE	01/20/2014	
12		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
13	NDC:50580-726-91	2500 in 1 CARTON	07/27/2018	
13		1 in 1 POUCH; Type 0: Not a Combination Product		
14	NDC:50580-726-92	50 in 1 TRAY	07/12/2018	

14		1 in 1 POUCH; Type 0: Not a Combination Product		
15	NDC:50580-726-93	3 in 1 CARTON	07/27/2018	
15		1 in 1 POUCH; Type 0: Not a Combination Product		
16	NDC:50580-726-94	1 in 1 PACKAGE	06/15/2020	
16		60 in 1 BOTTLE; Type 0: Not a Combination Product		
17	NDC:50580-726-95	1 in 1 PACKAGE	06/15/2020	
17		90 in 1 BOTTLE; Type 0: Not a Combination Product		
18	NDC:50580-726-96	5 in 1 CARTON	05/30/2020	
18		1 in 1 POUCH; Type 0: Not a Combination Product		
19	NDC:50580-726-97	14 in 1 CARTON	05/30/2020	
19		1 in 1 POUCH; Type 0: Not a Combination Product		
20	NDC:50580-726-05	50 in 1 CARTON	03/01/2023	
20		1 in 1 POUCH; Type 0: Not a Combination Product		
21	NDC:50580-726-25	2500 in 1 CASE	03/01/2023	
21		1 in 1 POUCH; Type 0: Not a Combination Product		
22	NDC:50580-726-71	1 in 1 CARTON	11/01/2024	
22		30 in 1 BOTTLE; Type 0: Not a Combination Product		
23	NDC:50580-726-72	1 in 1 CARTON	11/01/2024	
23		40 in 1 BOTTLE; Type 0: Not a Combination Product		
24	NDC:50580-726-73	1 in 1 CARTON	11/01/2024	
24		60 in 1 BOTTLE; Type 0: Not a Combination Product		
25	NDC:50580-726-74	1 in 1 CARTON	11/01/2024	
25		90 in 1 BOTTLE; Type 0: Not a Combination Product		
26	NDC:50580-726-45	1 in 1 CARTON	07/31/2025	
26		45 in 1 BOTTLE; Type 0: Not a Combination Product		
27	NDC:50580-726-75	1 in 1 CARTON	07/31/2025	
27		75 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019835	01/01/2008	

**Labeler** - Kenvue Brands LLC (118772437)