

ZYRTEC ALLERGY- cetirizine hydrochloride tablet, film coated
Johnson & Johnson Consumer Inc.

Zyrtec[®] 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 clamshell is opened, or if foil inner seal imprinted with "ZYRTEC®" 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 50580-726-36

ZYRTEC®

ALLERGY

Cetirizine HCl tablets

10 mg /antihistamine

Indoor & Outdoor Allergies

24

hour

Relief of

- Sneezing

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

30 Tablets
10 mg each

(Actual Size)

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

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Drug Facts (continued)

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ZYRTEC[®]

Cetirizine HCl tablets
10 mg / antihistamine

ALLERGY

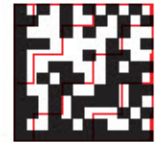
Indoor & Outdoor Allergies

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

Active ingredient made in Switzerland

Distributed by:
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McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA |
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US 7,866,475

30040818



ZYRTEC ALLERGY

cetirizine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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)	
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

Color	white	Score	2 pieces
Shape	RECTANGLE (rounded-off rectangular biconvex tablet)	Size	9mm
Flavor		Imprint Code	ZYRTEC;10;MG
Contains			

Packaging

#	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	12/31/2022
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-	75 in 1 PACKAGE, COMBINATION; Type 0: Not a	01/01/2008	

11	726-66	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	2500 in 1 CASE	03/01/2023	
20		1 in 1 POUCH; Type 0: Not a Combination Product		
21	NDC:50580-726-25	50 in 1 CARTON	03/01/2023	
21		1 in 1 POUCH; 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 - Johnson & Johnson Consumer Inc. (878046358)

Revised: 5/2023

Johnson & Johnson Consumer Inc.