

CHILDRENS ZYRTEC ALLERGY- cetirizine hydrochloride tablet, orally disintegrating
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

Childrens 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

Tablet melts in mouth. Can be taken with or without water.

one 10 mg tablet once daily; do not

adults and children 6 years and over	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). Avoid high humidity.
- **do not use if blister unit is torn or broken**

Inactive ingredients

amino methacrylate copolymer, anhydrous citric acid, colloidal silicon dioxide, crospovidone, flavors, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, sodium bicarbonate, sodium starch glycolate, sucralose

Questions?

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

PRINCIPAL DISPLAY PANEL

Original Prescription Strength

NDC 50580-782-12

Children's
Zyrtec® ALLERGY

Cetirizine HCl orally disintegrating tablets
10 mg/antihistamine

Indoor + Outdoor
Allergies

Dissolve Tabs

6 yrs.
& older
10mg each

Citrus Flavor

24
hour

Relief of

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

Actual
Size

Melts In
Your Mouth

12 ORALLY DISINTEGRATING TABLETS



Melts In Your Mouth

12 ORALLY DISINTEGRATING TABLETS

Active ingredient made in Switzerland
Distributed by: **JOHNSON & JOHNSON CONSUMER INC.**
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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Dissolve Tabs

Children's **ZYRTEC** ALLERGY

Drug Facts	
Active ingredient (in each tablet) Cetirizine HCl 10 mg.....Antihistamine	
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> runny nose sneezing itching of the nose or throat itchy, watery eyes 	
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 <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> breast-feeding: not recommended if pregnant: ask a health professional before use. 	
Questions? call 1-800-343-7805 (toll-free) or 215-273-8755 (collect)	
Other information <ul style="list-style-type: none"> store between 20° to 25°C (68° to 77°F). Avoid high humidity; do not use if blister unit is torn or broken 	
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adults 65 years and over ask a doctor	children under 6 years of age ask a doctor
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The trade dress of this ZYRTEC® package is subject to trademark protection.

LOT EXP

Children's **ZYRTEC** ALLERGY

Dissolve Tabs

Original Prescription Strength

NDC 50580-782-12



Children's ZYRTEC®

Indoor + Outdoor Allergies



CHILDRENS ZYRTEC ALLERGY

cetirizine hydrochloride tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-782
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
dimethylaminoethyl methacrylate - butyl methacrylate - methyl methacrylate copolymer (UNII: 905HNO1SIH)	
anhydrous citric acid (UNII: XF417D3PSL)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
crospovidone (15 MPA.S AT 5%) (UNII: 68401960MK)	
hydroxypropyl cellulose (70000 WAMW) (UNII: 6607AQV0RT)	
magnesium stearate (UNII: 70097M6B0)	
mannitol (UNII: 3OWL53L36A)	
microcrystalline cellulose (UNII: OP1R32D61U)	
sodium bicarbonate (UNII: 8MDF5V39QO)	
sodium starch glycolate Type A Potato (UNII: 5856J3G2A2)	
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	11mm
Flavor	CITRUS	Imprint Code	Z10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-782-12	2 in 1 CARTON	01/20/2014	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-782-24	4 in 1 CARTON	01/20/2014	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-782-01	2 in 1 PACKAGE	01/20/2014	
3		4 in 1 CARTON		
3		6 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	NDA022578	01/20/2014	

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

Revised: 3/2020

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division