CHILDRENS ZYRTEC- cetirizine hydrochloride syrup
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

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Children's ZYRTEC®

Drug Facts

Active ingredient (in each 5 mL)

Cetirizine HCl 5 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

- use only with enclosed dosing cup
- find right dose on chart below
- mL = milliliter

adults and children 6 years and over	5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours.
adults 65 years and over	5 mL once daily; do not take more than 5 mL in 24 hours.
children 2 to under 6 years of age	2.5 mL once daily. If needed, dose can be increased to a maximum of 5 mL once daily or 2.5 mL every 12 hours. Do not give more than 5 mL in 24 hours.
children under 2 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 carton is opened or if carton tape or bottle wrap imprinted "SAFETY SEAL®" is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, flavors, propylene glycol, purified water, sodium benzoate,sorbitol solution, sucralose

Questions?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-730-05

Children's
ZYRTEC®
ALLERGY

Cetirizine HCl
***1 mg /ml** oral solution*
antihistamine

Indoor & Outdoor Allergies

24
hour
Relief of

- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**

- **Itchy Throat or Nose**

2 yrs.
& older

Grape
Syrup

Dye-Free • Sugar-Free

4 fl oz (118 ml)
Dosing Cup Included

CHILDRENS ZYRTEC

cetirizine hydrochloride syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-730

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetirizine Hydrochloride (UNII: 64O047KTOA) (Cetirizine - UNII:YO7261ME24)	Cetirizine Hydrochloride	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-730-05	1 in 1 CARTON	07/13/2015	
1		118 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		
2	NDC:50580-730-06	2 in 1 PACKAGE	07/31/2015	
2		1 in 1 CARTON		
2		118 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		
3	NDC:50580-730-01	1 in 1 CARTON	01/16/2017	
3		30 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		
4	NDC:50580-730-17	3 in 1 PACKAGE	12/03/2018	
4		1 in 1 TRAY		
4		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
5	NDC:50580-730-18	2 in 1 PACKAGE	12/03/2018	
5		1 in 1 CARTON		
5		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
6	NDC:50580-730-19	1 in 1 CARTON	06/16/2020	
6		240 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-		

6	Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022155	06/01/2009	

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

Revised: 5/2020 Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division