CHILDRENS ALLERGY RELIEF - cetirizine hydrochloride solution Strategic Sourcing Services

ACTIVE INGREDIENT(S)

(in each 5 mL) Cetirizine Hydrochloride USP 5mg

PURPOSE

Antihistamine

USE(S)

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 year	rs5 mL or 10 mL once daily depending upon		
and over	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 year	s2.5 mL once daily. If needed, dose can be		
of age	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 o	ofask a doctor		
age			
consumers with liver o	orask a doctor		
kidney disease			

Other Information

- store between 20° to 25°C (68° to 77°F)
- do not use if carton is opened or bottle wrap imprinted "SAFETY SEAL®"

is broken or missing

see top panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, flavors, non crystallizing sorbitol solution, propylene glycol, purified water, sodium benzoate and sucralose.

Questions?

call **833-358-6431**

Distributed by:

McKesson Corp., via Strategic Sourcing Services, LLC., Memphis TN 38141

PRINCIPAL DISPLAY PANEL

Cetirizine Hydrochloride Oral Solution USP, 1 mg/1 mL-container label



Cetirizine Hydrochloride Oral Solution USP, 1 mg/1 mL-carton label





sunmark[®]

COMPARE TO CHILDREN'S ZYRTEC® ACTIVE INGREDIENT*

Children's all day allergy

Cetirizine Hydrochloride Oral Solution USP 1 mg/mL antihistamine

Indoor & Outdoor Allergies

Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose



Dosing cup included

4 FL OZ (118 mL) **Gluten Free**

2068760

Exp. Date:

Batch Coding Un Varnish for

<mark>sun</mark>mark[®]

COMPARE TO CHILDREN'S ZYRTEC® ACTIVE INGREDIENT* NDC 70677-0149-1

Children's all day allergy

Cetirizine Hydrochloride Oral Solution USP 1 mg/mL antihistamine

2 years & older

Indoor & Outdoor Allergies

Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

 Dye Free Sugar Free **GRAPE FLAVOR** 4 FL OZ (118 mL)

Dosing cup included

Gluten Free

Drug Facts

Active ingredient (in each 5 mL)

Purpose Cetirizine Hydrochloride USP 5 mg. Antihistamin

temporarily relieves these symptoms due to hay feve 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 i 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
 avcid 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 madical help or contact a Poison Control Center right away. (1-800-222-1222)

Important: Read all product information before using. Keep this box for important information. This product is intended for use in children.

Drug Facts (continued)

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

adults and 5 mL or 10 mL once daily depending children 6 years and over upon severity of symptoms; do not take more than 10 mL in 24 hours. adults 65 years and over 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 2 to under 6 years of ask a doctor children under 2 years of age

consumers with liver or kidney ask a doctor

Other information

store between 20° to 25°C (68° to 77°F)

Do not use if carton is opened or buttle wrap imprinted "SAFTEY SEAL" is broken or missing

see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, flavors, non crystallizing sorbitol solution, propylene glycol, purified water, sodium benzoate and sucralose.

Questions? Call 833-358-6431 from 9 AM to 7 PM EST, Monday-Friday

*This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., distributor of Children's Zyrtec[®].

Dosing cup should be washed and left to air dry after each use. Distributed by: McKesson Corp., via Strategic Sourcing Services, LLC., Memphis TN 38141 © 2003 McKesson Corporation Please visit us at www.sunmarkbrand.com Money back guarantee

Product of India

REV: 06/2022



Lamination or Print or Varnish Glueing Area Must be free from

CHILDRENS ALLERGY RELIEF

cetirizine hydrochloride solution

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:70677-0149

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE -	CETIRIZ INE	1 mg		

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
SORBITOL (UNII: 506T60A25R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

Product Characteristics		
Color	yellow (Colorless to Yellow)	Score
Shape		Size
Flavor	GRAPE	Imprint Code
Contains		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677- 0149-1	1 in 1 CARTON	07/21/2022	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA210622	07/21/2022		

Labeler - Strategic Sourcing Services (116956644)

Establishment					
Name	Address	ID/FEI	Business Operations		
Hetero Labs Limited Unit III		676162024	manufacture(70677-0149)		