CHILDRENS CETIRIZINE HYDROCHLORIDE- cetirizine hcl solution
Proficient Rx LP

Major Pharmaceuticals Children’s Cetirizine Hydrochloride Oral Solution 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 printed neckband is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, artificial grape flavor, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions or comments?

1-800-616-2471

Package/Label Principal Display Panel

COMPARE TO the active ingredient of CHILDREN'S ZYRTEC®

Children’s Cetirizine Hydrochloride Oral Solution 1 mg/mL

Antihistamine

ALLERGY

INDOOR & OUTDOOR ALLERGIES

24 HOUR RELIEF OF:

Sneezing / Runny Nose

Itchy, Watery Eyes / Itchy Throat or Nose

4 FL OZ

24 Hour

(118 mL)

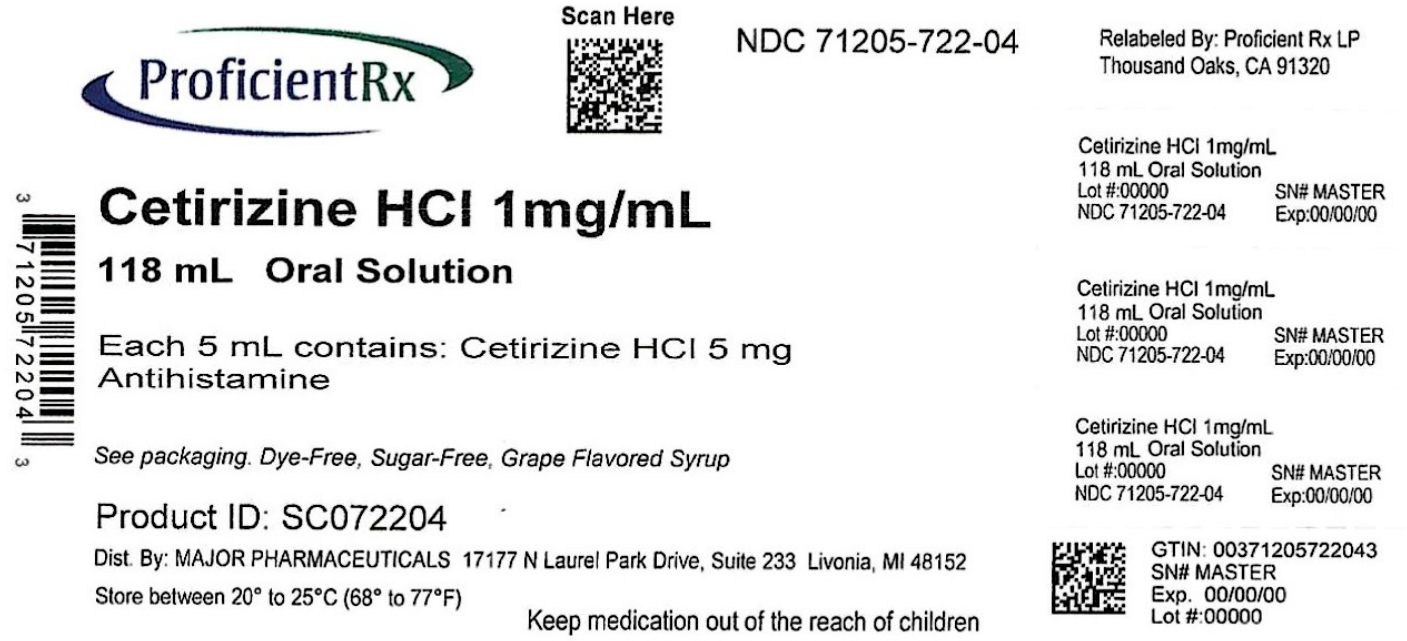
2yrs & older

Dosing Cup Included

Dye-Free

Sugar-Free

Grape Flavored Syrup



CHILDRENS CETIRIZINE HYDROCHLORIDE

cetirizine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71205-722(NDC:0904-6765)
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 (UNII: 506T60A25R)	
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:71205-722-04	1 in 1 CARTON	11/17/2022	
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	ANDA204226	08/22/2018	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-722) , RELABEL(71205-722)