

DYE FREE CHILDRENS CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
Precision Dose, Inc.

DYE FREE CHILDREN'S CETIRIZINE HYDROCHLORIDE
ORAL SOLUTION

Grape Flavor

5 mg/5 mL

For Hospital Use Only

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 as directed per healthcare professional.
- 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)
- See individual label or shipper for lot number and expiration date.

Inactive ingredients

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

Dye Free, Gluten Free, Sugar Free**How Supplied**

NDC 68094-004-62
5 mL per unit dose cup
Thirty (30) cups per shipper

Distributed By
Perrigo Company
Allegan, MI 49010

Packaged By
Precision Dose, Inc.
South Beloit, IL 61080

LI1060 Rev. 05/16

PRINCIPAL DISPLAY PANEL - 5 mL Cup Label

NDC 68094-004-59
PrecisionDose™

Children's CETIRIZINE HCl**Oral Solution**

5 mg/5 mL

DYE

FREE

Pkg: Precision Dose, Inc., S. Beloit, IL 61080



DYE FREE CHILDRENS CETIRIZINE HYDROCHOLRIDE

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68094-004(NDC:0113-0503)
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:68094-004-62	3 in 1 CASE	10/26/2016	
1		10 in 1 TRAY		
1	NDC:68094-004-59	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204226	10/26/2016	

Labeler - Precision Dose, Inc. (035886746)