

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
Bryant Ranch Prepack**

Perrigo Children's Cetirizine Hydrochloride Oral Solution 1 mg/mL 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

artificial grape flavor, glacial acetic acid, glycerin, methylparaben, natural banana flavor, propylene glycol, propylparaben, purified water, sodium acetate, sucrose

Questions or comments?

1-800-719-9260


HOW SUPPLIED

Children's Cetirizine Hydrochloride Oral Solution 1 mg/mL

- NDC 72162-2339-2: 118 mL in a BOTTLE

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Children's Cetirizine Hydrochloride Oral Solution 1 mg/mL

 GTIN 00363629106424 Lot LOT123 Exp 10/31/2025 SN 1234567890	Drug Facts Active ingredient (in each 5 mL) Cetirizine HCl 5 mg Antihistamine Purpose
	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).
	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. •Dye-Free •Grape Syrup •Indoor & Outdoor Allergies.
	Directions •use only with enclosed dosing cup •find right dose on chart below •mL = milliliter
	Inactive Ingredients artificial grape flavor, glacial acetic acid, glycerin, methylparaben, natural banana flavor, propylene glycol, propylparaben, purified water, sodium acetate, sucrose.

NDC 72162-2339-2

**Children's
Cetirizine
Hydrochloride
Oral Solution**

1 mg/mL



Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

4 FL OZ (118 mL)



Extended Label

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

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72162-2339(NDC:45802-974)
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
ACETIC ACID (UNII: Q40Q9N063P)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	YELLOW (Pale Yellow)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72162-2339-2	1 in 1 CARTON	06/18/2024	
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	ANDA090254	04/15/2008	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(72162-2339) , RELABEL(72162-2339)

Revised: 6/2024

Bryant Ranch Prepack