

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

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**Children's Cetirizine Hydrochloride Oral Solution, USP 1 mg/mL (Bubble Gum & Grape Flavor)**

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

**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.
- Side effects occur: You may report side effects to FDA at 1-800-FDA-1088.

**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)
- Protect from light
- **do not use if carton is opened or if carton tape or bottle wrap imprinted "SEALED FOR YOUR PROTECTION" is broken or missing**
- see bottom panel for lot number and expiration date

**Inactive ingredients**

**Bubble Gum Syrup:** anhydrous citric acid, artificial bubble gum flavor, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

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

## Questions?

Call **1-888-344-9603** (toll-free)

Manufactured by:

**Quagen Pharmaceuticals LLC**  
West Caldwell, NJ 07006

51001 & 51002  
Rev. 10/18

## HOW SUPPLIED

NDC: 72162-2073-2: 118 mL in a BOTTLE

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

Protect from light

do not use if carton is opened or if carton tape or bottle wrap imprinted "SEALED FOR YOUR PROTECTION" is broken or missing

## Cetirizine Hydrochloride Oral Solution



GTIN  
Lot  
Exp  
SN

Each 5 mL contains: Cetirizine HCl 5 mg.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light.

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.

Do not use if bottle wrap imprinted "Sealed for your Protection" is broken or missing.

NDC 72162-2073-2

**Cetirizine Hydrochloride  
Oral Solution, USP**

**1 mg/mL**



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

4 fl oz (118 mL)

Manufactured by:  
Quagen Pharmaceuticals  
LLC,



## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72162-2073(NDC:70752-104)
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)			CETIRIZINE HYDROCHLORIDE	1 mg in 1 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:72162-2073-2	1 in 1 CARTON	08/15/2023	
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	ANDA212266	10/15/2022		

**Labeler** - Bryant Ranch Prepack (171714327)

**Registrant** - Bryant Ranch Prepack (171714327)

### Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(72162-2073) , RELABEL(72162-2073)