CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
QUAGEN PHARMACEUTICALS LLC

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

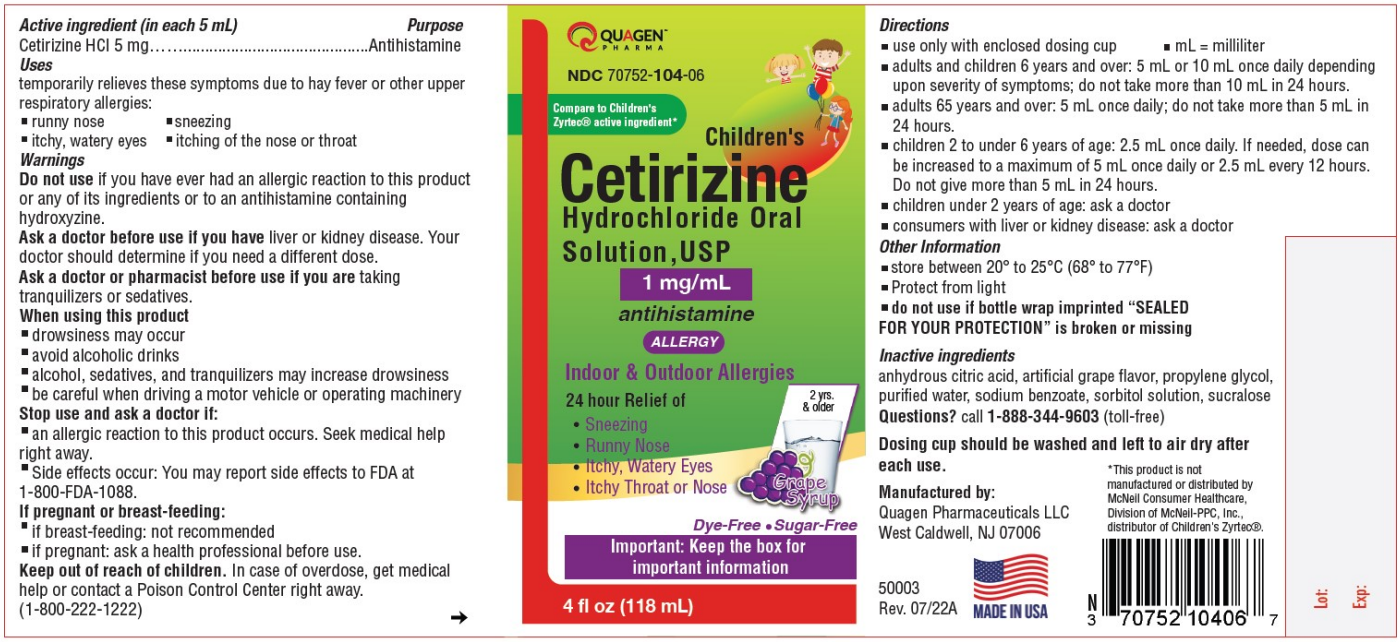
Questions?

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

Manufactured by:
Quagen Pharmaceuticals LLC
West Caldwell, NJ 07006

51001 & 51002
Rev. 10/18

PRINCIPAL DISPLAY PANEL - Grape Flavor - Container Label



PRINCIPAL DISPLAY PANEL - Grape Flavor-Carton Label

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70752-103
Route of Administration	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	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70752-103-06	1 in 1 CARTON	10/15/2022	
1		118 mL in 1 BOTTLE, PLASTIC; 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	

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70752-104
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE -	CETIRIZINE	1 mg

UNII:YO7261ME24)	HYDROCHLORIDE	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:70752-104-06	1 in 1 CARTON	10/15/2022	
1		118 mL in 1 BOTTLE, PLASTIC; 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 - QUAGEN PHARMACEUTICALS LLC (073645339)

Registrant - QUAGEN PHARMACEUTICALS LLC (073645339)

Establishment

Name	Address	ID/FEI	Business Operations
QUAGEN PHARMACEUTICALS LLC		080281331	manufacture(70752-103, 70752-104) , pack(70752-103, 70752-104)

Revised: 5/2023 QUAGEN PHARMACEUTICALS LLC