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)

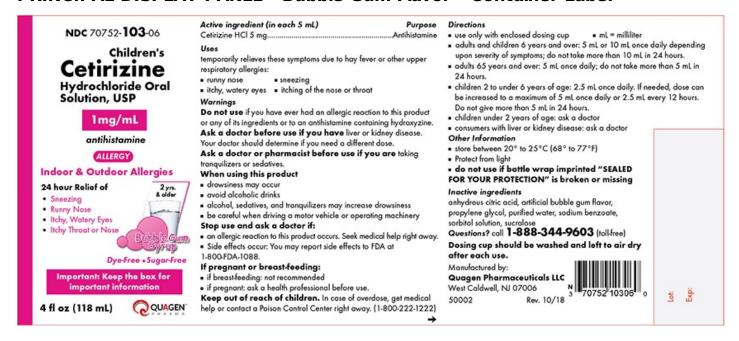
Manufactured by:

Quagen Pharmaceuticals LLC

West Caldwell, NJ 07006

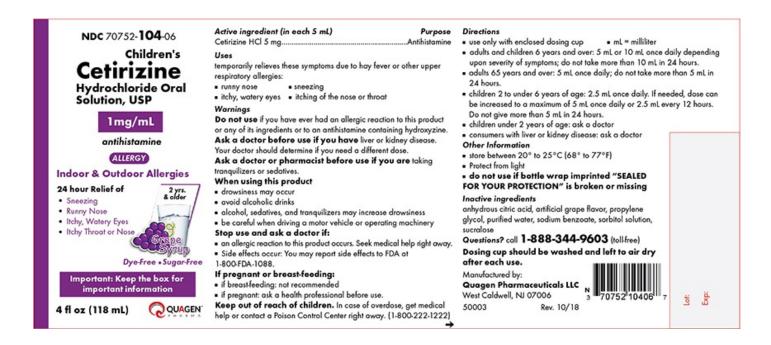
51001 & 51002 Rev. 10/18

PRINCIPAL DISPLAY PANEL - Bubble Gum Flavor - Container Label



PRINCIPAL DISPLAY PANEL - Bubble Gum Flavor - Carton Label





PRINCIPAL DISPLAY PANEL - Grape Flavor-Carton Label



NDC 70752-104-06

Children's Cetirizine

Hydrochloride Oral Solution, USP

1mg/mL

antihistamine

ALLERGY

Indoor & Outdoor Allergies

24 hour Relief of

- Sneezing
- · Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose



Dye-Free • Sugar-Free

Dosing Cup Included

Dosing cup should be washed and left to air dry after each use.

Important: Keep the box for important information

4 fl oz (118 mL)



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Warnings

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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

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If pregnant or breast-feeding:

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 if pregnant: ask a health professional before use

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NDC 70752-104-06

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Hydrochloride Oral Solution, USP

1mg/mL

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Lot:

Exp:



Drug Facts (Continued)

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 FOR YOUR PROTECTION" 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? Call 1-888-344-9603 (toll-free)

Manufactured by:

Quagen Pharmaceuticals LLC

West Caldwell, NJ 07006

Rev. 10/18

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: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE 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	
NDC:70752- 103-06	1 in 1 CARTON	05/17/2019		
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	05/17/2019		

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: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE HYDROCHLORIDE	1 mg in 1 mL	

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SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging				
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1 NDC:70752- 104-06	1 in 1 CARTON	05/17/2019		
1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing En Category Citation Date Date				
ANDA	ANDA212266	05/17/2019		

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)