

CHILDRENS ALLERGY RELIEF - cetirizine hydrochloride solution
Camber Consumer Care Inc

Active ingredient

(in each 5 mL)

Cetirizine Hydrochloride USP 5mg

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 bottle wrap imprinted “SAFETY SEAL” is broken or missing**
- see top panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, flavors, non crystallizing sorbitol solution, propylene glycol,

purified water, sodium benzoate and sucralose.

Questions?

call **1-888-588-1418**

Distributed by:
Camber Consumer Care, Inc.
Piscataway, NJ 08854, USA.

PRINCIPAL DISPLAY PANEL

Cetirizine Hydrochloride Oral Solution USP, 1 mg/1 mL-container label



130 mm

Layer_1 Back Side

<p>Active ingredient (in each 5 mL) Cetirizine Hydrochloride USP 5 mg....Antihistamine</p> <p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat <p>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,</p>	<p>Purpose a different dose.</p> <p>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding:</p> <ul style="list-style-type: none"> ■ if breast-feeding: not recommended ■ if pregnant: ask a health professional before use. 	<p>Glue Area</p>
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Layer_2 Front Side

<p>Glue Area</p>	<p>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)</p> <p>Directions</p> <ul style="list-style-type: none"> ■ use only with enclosed dosing cup ■ 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 	<p>12 hours. Do not give more than 5 mL in 24 hours.</p> <ul style="list-style-type: none"> ■ children under 2 years of age: ask a doctor ■ consumers with liver or kidney disease: ask a doctor <p>Other information</p> <ul style="list-style-type: none"> ■ store between 20° to 25°C (68° to 77°F) ■ do not use if bottle wrap imprinted "SAFETY SEAL" is broken or missing <p>Inactive ingredients anhydrous citric acid, flavors, non crystallizing sorbitol solution, propylene glycol, purified water, sodium benzoate and sucralose</p> <p>Questions? call 1-888-588-1418</p> <p>Dosing cup should be washed and left to air dry after each use</p>
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Cetirizine Hydrochloride Oral Solution USP, 1 mg/1 mL-carton label

Unvarnished Area

9125012

NDC 69230-316-11

CAMBER
CONSUMER CARE

*Compare to the active ingredient in Children's Zyrtec®

Children's Allergy Relief

Cetirizine Hydrochloride Oral Solution USP 1 mg/mL

Antihistamine

Indoor & Outdoor Allergies

24
HOUR

24-hour relief of

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

For ages 2 years and older

Dye-free
Sugar free

Dosing Cup Included

GRAPE FLAVOR

4 fl oz (118 mL)

Drug Facts

Active ingredient (in each 5 mL)	Purpose
Cetirizine Hydrochloride USP 5 mg Antihistamine	
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:	
<ul style="list-style-type: none"> ■ runny nose ■ itchy, watery eyes 	<ul style="list-style-type: none"> ■ sneezing ■ 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	
<ul style="list-style-type: none"> ■ 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:	
<ul style="list-style-type: none"> ■ 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	
<ul style="list-style-type: none"> ■ 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.

NDC 69230-316-11

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Children's Allergy Relief

Cetirizine Hydrochloride Oral Solution USP 1 mg/mL

Antihistamine

Indoor & Outdoor Allergies

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GRAPE FLAVOR

4 fl oz (118 mL)

Drug Facts (continued)

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
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<ul style="list-style-type: none"> ■ store between 20° to 25°C (68° to 77°F) ■ Do not use if carton is opened or bottle wrap imprinted "SAFETY SEAL" is broken or missing ■ see top panel for lot number and expiration date 	
Inactive ingredients anhydrous citric acid, flavors, non-crystallizing sorbitol solution, propylene glycol, purified water, sodium benzoate and saccharose.	
Questions? call 1-888-588-1418	

* This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Zyrtec®.

N 311692301516115

Mfg. Lic. No.: 24/MD/TS/2016/F/G

Distributed by:
Camber Consumer Care, Inc.
Piscataway, NJ 08854, USA.

CHILDRENS ALLERGY RELIEF
cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69230-316
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)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	yellow (Colorless to Yellow)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69230-316-11	1 in 1 CARTON	03/13/2019	
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	ANDA210622	03/13/2019	

Labeler - Camber Consumer Care Inc (079539968)

Establishment

Name	Address	ID/FEI	Business Operations
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Hetero Labs Limited Unit III		676162024	manufacture(69230-316)
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Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	manufacture(69230-316)

Revised: 3/2024

Camber Consumer Care Inc