CHILDRENS ALLERGY RELIEF - cetirizine hydrochloride solution
Camber Consumer Care

ACTIVE INGREDIENT(S)

(in each 5 mL)
Cetirizine Hydrochloride USP 5mg

PURPOSE

Antihistamine

USE(S)

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.

Mfg. Lic. No.: 22/RR/AP/2001/F/R

PRINCIPAL DISPLAY PANEL

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

NDC 69230-316-11

Mfg. Lic. No.: 22/RR/AP/2001/F/R

Peel to open

CAMBER CONSUMER CARE

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

Children's Allergy Relief

24 HOUR

Cetirizine Hydrochloride Oral Solution USP
1 mg/mL / Antihistamine

Indoor & Outdoor Allergies

24-hour relief of
. Sneezing
. Runny nose
. Itchy, watery eyes
. Itchy throat or nose

For ages 2 years & older

Dye-free

Sugar free

GRAPE FLAVOR

4 fl oz (118 mL)

LOT

EXP

Unvarnished Area

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

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

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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:

- 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
- 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 bottle wrap imprinted "SAFETY SEAL®" is broken or missing**

Inactive ingredients

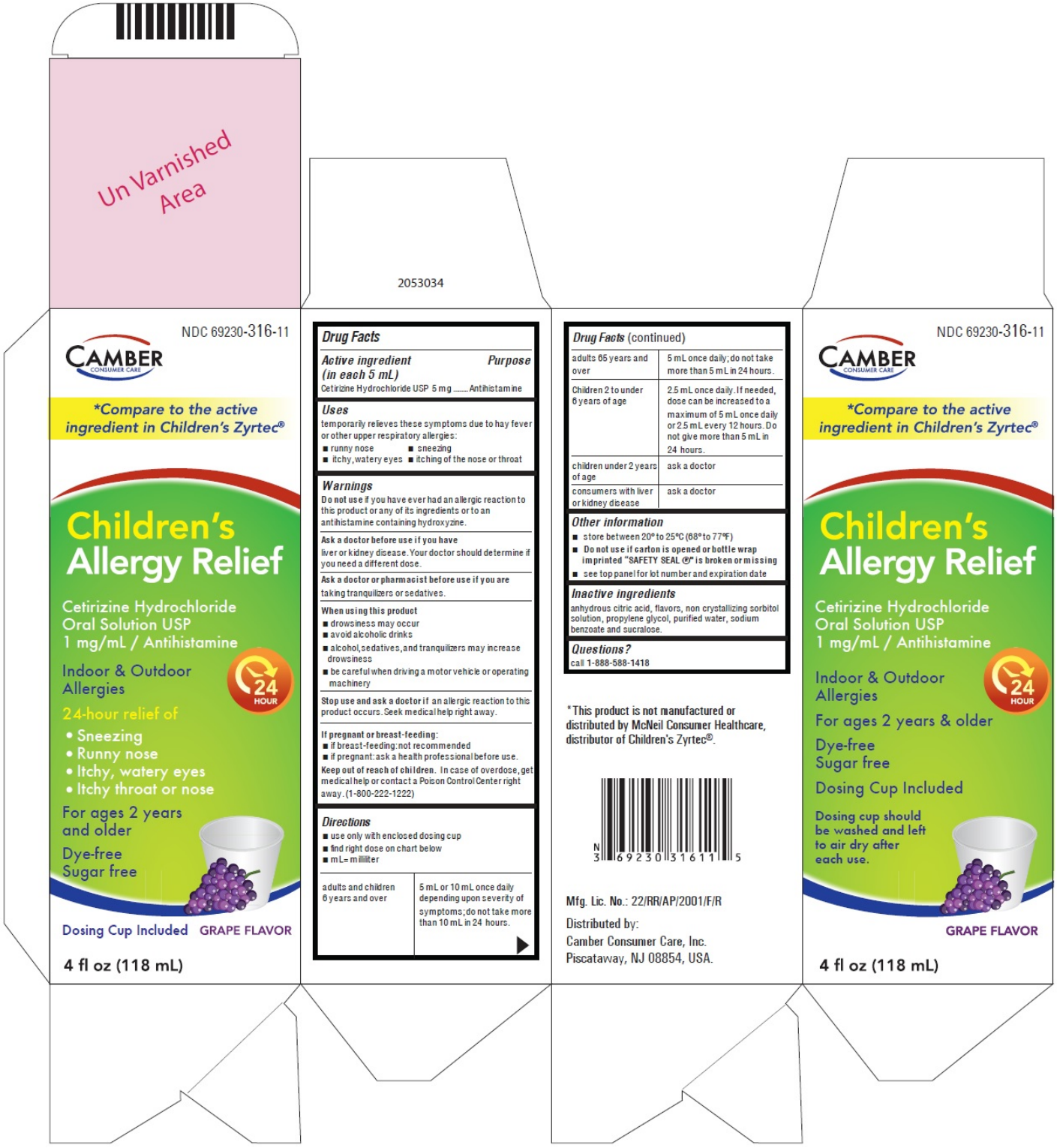
anhydrous citric acid, flavors, non crystallizing sorbitol solution, propylene glycol, purified water, sodium benzoate and sucralose

Questions?

call 1-888-588-1418

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

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



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: 059QF0KO0R)	
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 (079539968)

Establishment

Name	Address	ID/FEI	Business Operations
Hetero Labs Limited Unit III		676162024	ANALYSIS(69230-316) , MANUFACTURE(69230-316)

Revised: 3/2019

Camber Consumer Care