

CHILDRENS ALLERGY- cetirizine hydrochloride solution
Publix Super Markets Inc

children's allergy

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.

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 of age 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

- **do not use if carton is opened or if imprinted safety seal is broken or missing**
- see bottom panel for lot number and expiration date
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

artificial grape flavor, glacial acetic acid, glycerin, methylparaben, natural and artificial banana flavor, propylene glycol, propylparaben, purified water, sodium acetate (anhydrous), sucralose

**DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.,
3300 PUBLIX CORPORATE PARKWAY
LAKELAND, FL 33811**

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 56062-102-08

AGES 2 YEARS
AND OLDER
INDOOR & OUTDOOR
ALLERGIES

children's
allergy

CETIRIZINE HYDROCHLORIDE
ORAL SOLUTION, 1 mg/mL
ALLERGY

ANTIHISTAMINE

24-hour relief of:

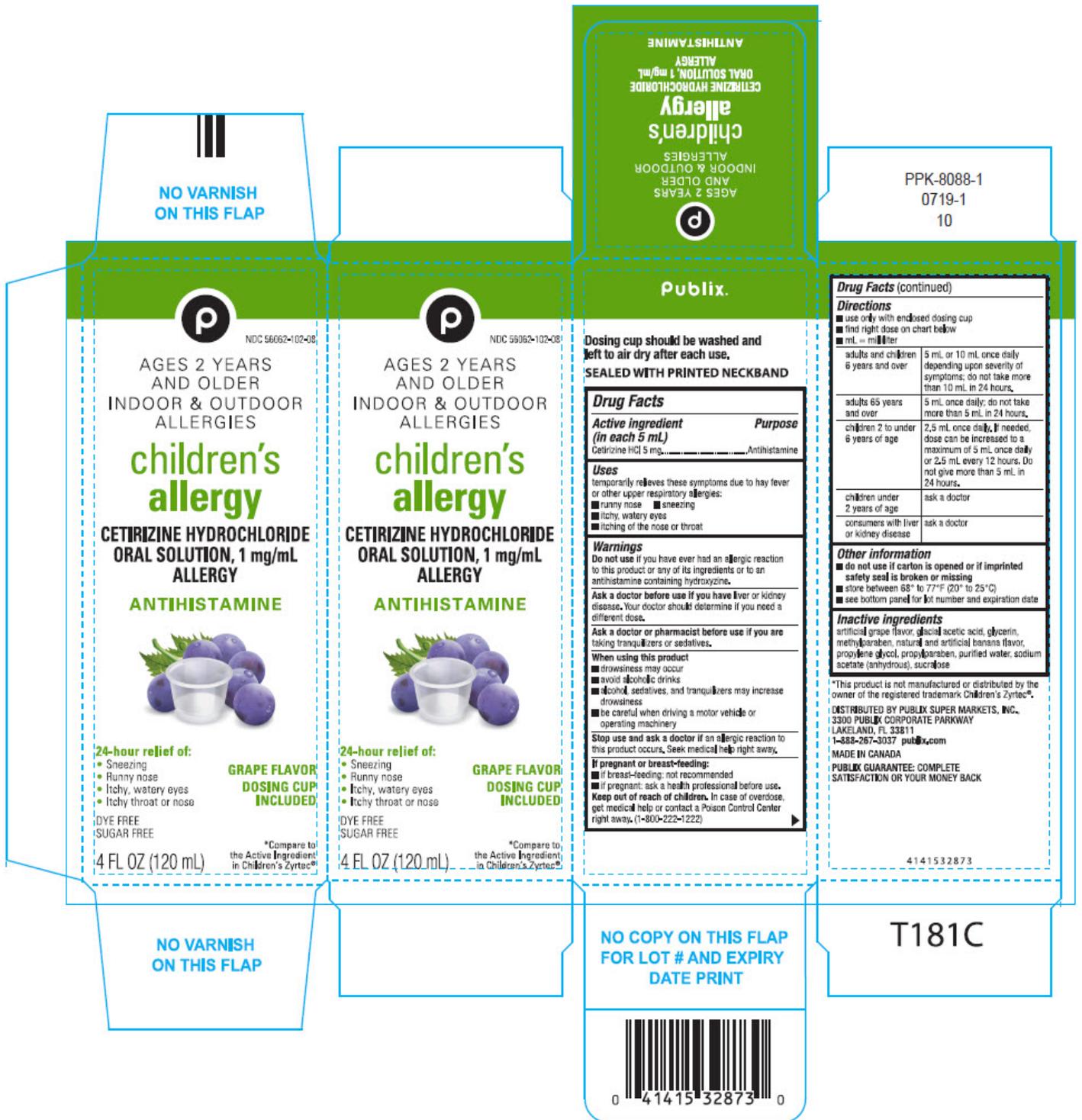
- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

GRAPE FLAVOR
DOSING CUP
INCLUDED

DYE FREE
SUGAR FREE

4 FL OZ (120 mL)

*Compare to
the Active Ingredient
in Children's Zyrtec[®]



CHILDRENS ALLERGY

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)		CETIRIZINE HYDROCHLORIDE	5 mg in 5 mL	
Inactive Ingredients				
Ingredient Name		Strength		
ACETIC ACID (UNII: Q40Q9N063P)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	yellow (colorless to slightly yellow)	Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-102-08	1 in 1 CARTON	11/04/2016	
1		120 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	ANDA090182	09/08/2011		

Labeler - Publix Super Markets Inc (006922009)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(56062-102)