

**CHILDRENS LORATADINE SUGAR FREE- loratadine solution**  
**CARDINAL HEALTH 110, LLC. DBA LEADER**

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**Children's Loratadine Oral Solution**  
**Sugar Free**

***Drug Facts***

**Active ingredient (in each 5 mL teaspoonful)**

Loratadine 5 mg

**Purpose**

Antihistamine

**Uses**

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- 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.

**Ask a doctor before use if you have** liver or kidney disease. Your doctor should determine if you need a different dose.

**When using this product** do not take more than directed. Taking more than directed may cause drowsiness.

**Stop use and ask a doctor if** an allergic reaction to this product occurs. Seek medical help right away.

**If pregnant or breast-feeding,** 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

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adults and                      2 teaspoonfuls (tsp) daily; do not

children 6 years and over	take more than 2 teaspoonfuls (tsp) in 24 hours
children 2 to under 6 years of age	1 teaspoonful (tsp) daily; do not take more than 1 teaspoonful (tsp) 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 bottle wrap imprinted with "SEALED FOR SAFETY" is broken or missing.**
- see bottom panel for lot number and expiration date
- store between 20° and 25°C (68° and 77°F)

### Inactive ingredients

butylated hydroxyanisole, glycerin, grape flavor, maltitol solution, masking agent, phosphoric acid, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium phosphate monobasic dihydrate, sorbitol solution, sucralose powder.

### Questions?

Call **1-866-923-4914**

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017

### PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

**LEADER™**

NDC 70000-0252-1

**Non-Drowsy †**  
**Children's**  
**Allergy**

**Loratadine Oral Solution**  
**USP, 5 mg/5 mL**  
**Antihistamine Allergy**  
**Indoor & Outdoor Allergies**

**Grape**Flavor  
Sugar Free  
Alcohol Free  
Dye Free

**24 Hour**

**Relief of:**

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

**COMPARE TO  
CHILDREN'S  
CLARITIN<sup>®</sup>**

active ingredient\*

**100% Money  
Back Guarantee**

**Ages 2 Years  
and Older**

†When taken as directed. See Drug Facts Panel.

**4 FL OZ (120 mL)**



## CHILDRENS LORATADINE SUGAR FREE

loratadine solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:7000-0252
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)		LORATADINE	5 mg in 5 mL

  

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	

  

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:70000-0252-1	1 in 1 CARTON	03/17/2017	
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	ANDA076805	03/17/2017	

**Labeler** - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

### Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(70000-0252)