# **LEADER CHILDRENS ALLERGY RELIEF- loratadine solution Cardinal Health 110, LLC. dba Leader**

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#### Cardinal Health Children's Allergy Relief 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

adults and children 6 years and over	2 teaspoonfuls (tsp) daily; do not 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 carton is opened, or if printed neckband is broken or missing
- store between 20° to 25°C (68° to 77°F)

#### **Inactive ingredients**

edetate disodium, glycerin, maltitol, monobasic sodium phosphate, natural and artificial grape flavor, phosphoric acid, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose

#### Questions or comments?

1-800-719-9260

## Package/Label Principal Display Panel

Non-Drowsy\*

Children's Allergy Relief

Loratadine Oral Solution USP, 5 mg/5 mL | Antihistamine

Indoor and Outdoor Allergies

Grape Flavor

24 Hour Relief of:

Sneezing

Runny Nose; Itchy, Watery Eyes

Itchy Throat or Nose

Sugar-Free

Alcohol-Free

Dye-Free

COMPARE TO CHILDREN'S CLARITIN  $^{\circledR}$  active ingredient

Ages 2 Years and Older

100% Money Back Guarantee

\*When Taken As Directed.

See Drug Facts Panel.

4 FL OZ (120 mL)



## LEADER CHILDRENS ALLERGY RELIEF

loratadine solution

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70000-0473 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
EDETATE DISODIUM (UNII: 7FLD91C86K)		
GLYCERIN (UNII: PDC6A3C0OX)		
MALTITOL (UNII: D65DG142WK)		
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)		
PHOSPHORIC ACID (UNII: E4GA8884NN)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Product Characteristics		
Color		Score
Shape		Size
Flavor	GRAPE	Imprint Code
Contains		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70000- 0473-1	1 in 1 CARTON	01/23/2020		
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	ANDA075728	01/23/2020		

## Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021 Cardinal Health 110, LLC. dba Leader