## CHILDRENS ALLERGY- loratadine solution Publix Super Markets Inc

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children's allergy

**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

years ariu uver	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 imprinted safety seal is broken or missing
- see bottom panel for expiration date
- store between 20° to 25°C (68° to 77°F)

#### Inactive ingredients

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

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

#### PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

**Publix** 

NDC 56062-092-08

**INDOOR & OUTDOOR ALLERGIES** 

### children's allergy

LORATADINE ORAL SOLUTION, 5 mg/5 mL

#### **ANTIHISTAMINE**

24-hour relief of:

- sneezing, runny nose
- itchy, watery eyes
- itchy throat or nose

Ages 2 yrs. and older

DYE FREE

SUGAR-FREE

Grape-Flavored Syrup

Dosing Cup Enclosed

\*Compare to Active Ingredient in Children's Claritin ®

24 Hour Non-Drowsy <sup>†</sup> <sup>†</sup>When taken as directed. See Drug Facts Panel

4 FL OZ (120 mL)



# **CHILDRENS ALLERGY**

loratadine solution

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:56062-092

**Route of Administration** ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength
I	LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg in 5 mL

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
SORBITOL (UNII: 506T60A25R)			
PHOSPHORIC ACID (UNII: E4GA8884NN)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM METABISULFITE (UNII: 4VON5FNS3C)			
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 50WK665956)			

Product Characteristics		
Color	yellow (colorless to slightly yellow)	Score
Shape		Size
Flavor	GRAPE (sugar free)	Imprint Code
Contains		

I	Packaging			
4	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-092- 08	1 in 1 CARTON	02/27/2010	
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	02/27/2010	

# **Labeler -** Publix Super Markets Inc (006922009)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Taro Pharmaceuticals Inc.		206263295	manufacture(56062-092)	

Revised: 5/2024 Publix Super Markets Inc