

CHILDRENS ALLERGY- loratadine solution
Publix Super Markets Inc

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

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 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

ANTI-HISTAMINE

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†

†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
Loratadine (UNII: 7AJ03BO7QN) (Loratadine - UNII:7AJ03BO7QN)	Loratadine	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
glycerin (UNII: PDC6A3C0OX)	
sorbitol (UNII: 506T60A25R)	
phosphoric acid (UNII: E4GA8884NN)	
polyethylene glycols (UNII: 3WJQ0SDW1A)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
sodium phosphate, monobasic, dihydrate (UNII: 5QWK665956)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-092-08	1 in 1 CARTON		
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)

Revised: 5/2015

Publix Super Markets Inc