

LORATADINE - loratadine solution
Major Pharmaceuticals, Inc

Children's Loratadine Oral Solution

Loratadine Oral Solution - Allergy

Active Ingredient: Loratadine 5 mg (in each 5 mL(teaspoonful)(TSP))

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 allergic reaction to this product or any of it's 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.

Directions

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

- **Each teaspoonful contains:** sodium 1 mg
- Safety Sealed. Do not use if imprinted seal around cap is broken or missing
- Store between 20° to 25°C (68° to 77°F)

Inactive ingredients

Butylated hydroxyanisole, citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium benzoate, sucralose.

Questions

1-800-616-2471

Distributed by:
Major Pharmaceuticals
31778 Enterprise Drive,
Livonia, MI 48150 USA

5 mg/5 mL
Loratadine
Children's
MAJOR
NDC 0904-6234-20

Drug Facts

Active ingredient Purpose
(in each 5 mL (teaspoonful) (TSP))
Loratadine 5 mg Antihistamine

Uses
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 ■ runny nose ■ itchy, watery eyes
 ■ sneezing ■ itching of the nose or throat

Warnings
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Questions or comments 1-800-616-2471

NDC 0904-6234-20

MAJOR

Grape Flavor
Ages 2 years and older

Children's
Loratadine
Oral Solution

Allergy

5 mg/5 mL
ANTI-HISTAMINE
Non-Drowsy*
24 Hour Relief of
 • Sneezing
 • Runny Nose
 • Itchy, Watery Eyes
 • Itchy Throat or Nose

Indoor and Outdoor Allergies

- Dye-Free
- Alcohol-Free
- Sugar-Free
- Grape Flavor

* When taken as directed. See Drug Facts Panel.

120 mL (4 FL OZ)

NDC 0904-6234-20

MAJOR

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120 mL (4 FL OZ)

MAJOR

Up to 24 Hours of Relief
Ages 2 years and older

Children's
Loratadine
Oral Solution

Allergy

5 mg/5 mL
ANTI-HISTAMINE
Non-Drowsy*
24-hour Relief
 • Dye-Free
 • Alcohol-Free
 • Sugar-Free
 • Grape Flavor

Dosage Cup Enclosed
SAVE THIS CARTON FOR FULL LABELING INFORMATION
See top flap of the carton for Control No. and Expiration Date.

Distributed by:
MAJOR® PHARMACEUTICALS
31778 Enterprise Drive,
Livonia, MI 48150 USA
M-82 Re-Order No. 265291 Rev. 10/12


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LORATADINE
loratadine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6234	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	Loratadine (UNII: 7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN)	Loratadine	5 mg in 5 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	anhydrous citric acid (UNII: XF417D3PSL)			
	butylated hydroxyanisole (UNII: REK4960K2U)			
	glycerin (UNII: PDC6A3C0OX)			
	propylene glycol (UNII: 6DC9Q167V3)			
	sodium benzoate (UNII: OJ245FE5EU)			
	sucralose (UNII: 96K6UQ3ZD4)			
	water (UNII: 059QF0KO0R)			
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE (grape flavor)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6234-20	120 mL in 1 CARTON		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077421	02/17/2011		

Labeler - Major Pharmaceuticals, Inc (191427277)

Revised: 6/2014

Major Pharmaceuticals, Inc