

**LORATADINE - loratadine solution**  
**Atlantic Biologicals Corps**

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**Children's Loratadine Oral Solution**

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**

ever had allergic reaction to this product or any of it's ingredients **Do not use if you have** liver or kidney disease. Your doctor should determine if you need a different dose. **Ask a doctor before use if you have**

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

an allergic reaction to this product occurs. Seek medical help right away. **Stop use and ask a doctor if** , ask a health professional before use. **If pregnant or breast-feeding**

. In case of overdose, get medical help or contact a Poison Control Center right away. **Keep out of reach of children**

**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**

- : sodium 1 mg **Each teaspoonful contains**
- 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

## LORATADINE SOLUTION

**NDC 17856-6234-05**

CHILDREN'S  
**Loratadine**  
*Oral Solution*  
Allergy  
**5 mg per 5 mL**  
Non-Drowsy\*  
ANTIHISTAMINE  
GRAPE FLAVOR  
AGES 2 years and older  
Dye Free / Alcohol Free / Sugar Free  
**UNIT DOSE 5 mL Cups**

**PACKAGING INFORMATION:**

Dosage per Cup: 5 mL  
Cup(s) per Case: 9

**See package insert for Drug Facts.**

**Other information:**

Each teaspoonful (TSP) contains: sodium 1 mg  
Store between 20° to 25°C (68° - 77°F)

**KEEP CHILDREN'S LORATADINE ORAL SOLUTION AND ALL  
MEDICINES OUT OF THE REACH OF CHILDREN**

Dist by: Major Pharmaceuticals  
Livonia, MI 48150, USA  
Repackaged by: UDose LLC, Miami, FL 33179  
Distributed by: Atlantic Biologicals Corp.  
20101 N.E. 16th Place  
Miami, FL 33179

**\*Retain box label and package insert for drug information.**

Questions or Comments:  
Call 1-800-509-7582

UDose LLC Lot No: 238562  
Mfg Lot No: 0575A  
Exp. Date: 01/11/2017



## LORATADINE

loratadine solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-6234(NDC:0904-6234)
<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
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: 059QF0K00R)	

### 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:17856-6234-2	5 mL in 1 CUP; Type 0: Not a Combination Product	05/03/2016	
2	NDC:17856-6234-5	5 mL in 1 CUP; Type 0: Not a Combination Product	08/16/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077421	02/17/2011	

**Labeler** - Atlantic Biologicals Corps (047437707)

**Registrant** - Atlantic Biologicals Corps (047437707)

### Establishment

Name	Address	ID/FEI	Business Operations
Atlantic Biologicals Corps		047437707	RELABEL(17856-6234) , REPACK(17856-6234)

Revised: 8/2016

Atlantic Biologicals Corps