

**LORATADINE - loratadine oral solution**  
**Aurohealth LLC**

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**Loratadine Oral Solution USP 5 mg/5 mL**

***Drug Facts***

***Active ingredient (in each 5 mL teaspoonful)***

Loratadine USP 5 mg

***Purpose***

Antihistamine

***Uses***

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- 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 (1-800-222-1222) right away.

***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***

- **each teaspoonful contains:** sodium 6 mg
- do not use if carton is opened, or if cap safety seal is broken or missing.
- store at 20° to 25°C (68° to 77°F)

#### ***Inactive ingredients***

artificial flavors, ascorbic acid, glycerin, maltitol, monobasic sodium phosphate monohydrate, phosphoric acid, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sorbitol, sucralose.

#### ***Questions or comments?***

Call 1-855-274-4122

Distributed by:

**AUROHEALTH LLC**

2572 Brunswick Pike

Lawrenceville, NJ 08648

Made in India

Code:TS/DRUGS/19/1993

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg/5 mL (60 mL Bottle)**

**NDC 58602-423-11**

**Ages**

**2 years  
and older**

**Loratadine**

**Oral Solution USP**

**5 mg/5 mL**

**Antihistamine**

***Non-Drowsy\****

**24 Hour Relief of:**

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

Do not use if carton is opened, or if cap safety seal is broken or missing.

- Dye-Free
- Sugar-Free
- Alcohol Free


## Indoor & Outdoor Allergies

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

**\* When taken as directed. See Drug Facts Panel.**

## Grape Flavor

2 FL OZ (60 mL)



NDC 58602-423-11

**Loratadine Oral Solution USP**  
5 mg/5 mL  
Antihistamine

**Non-Drowsy\***  
24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

**Adult & Children Allergies**

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

**\*When taken as directed. See Drug Facts Panel.**

**Grape Flavor**

**2 FL OZ (60 mL)**

**Drug Facts**

**Active ingredient**  
(in each 5 mL teaspoonful)  
Loratadine USP 5 mg.....

**Purpose**  
Antihistamine

Uses temporarily relieve these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- 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 breastfeeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center (1-800-222-1222) right away.

**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** • each teaspoonful contains: sodium 6 mg • do not use if carton is opened, or if cap safety seal is broken or missing. • store at 20° to 25°C (68° to 77°F)

**Inactive ingredients** artificial flavors, ascorbic acid, glycerin, maltitol, monobasic sodium phosphate, monohydrate, phosphoric acid, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sorbitol, sucralose.

**Questions or comments?** Call 1-855-2-74-41-22

Distributed by: AUROHEALTH LLC  
2572 Brunsford Pike, Lawrenceville, NJ 08648  
Code: TS01RUGS/19/1908      Made in India

1672271d  
7255-WL

\* Lot: XXXXXXXX  
EXP: MM/YYYY  
Prefix & Variables of Lot, EXP shall be printed online during packing.

## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg/5 mL Carton (60 mL)

NDC 58602-423-11

#Compare to the active ingredient in children's Claritin®

**Ages**

**2years  
and older**

**Loratadine  
Oral Solution USP  
5 mg/5 mL**

**Antihistamine**

***Non-Drowsy\****

**24 Hour Relief of:**

- *Sneezing*
- *Runny Nose*
- *Itchy, watery Eyes*
- *Itchy Throat or Nose*

**Indoor & Outdoor Allergies**

**Dosing Cup Included**

- *Dye-Free*

Contains sodium  
metabisulfite, a sulfite  
that may cause  
allergic-type reactions.

***\* When taken as directed.***

***See Drug Facts Panel.***

**Grape**

**Flavor**

**2 FL OZ (60 mL)**

### Drug Facts

**Active ingredient** **Purpose**  
(in each 5 mL teaspoonful)  
Loratadine USP 5 mg ..... Antihistamine

#### Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- 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 (1-800-222-1222) right away.

#### 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
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children under 2 years of age	ask a doctor
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consumers with liver or kidney disease	ask a doctor
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### Drug Facts (continued)

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**Questions or comments?**  
Call 1-855-274-4122

\*This product is not manufactured or distributed by Bayer Healthcare LLC distributor of Children's Claritin®

**Do not use if carton is opened, or if cap safety seal is broken or missing.**

- Sugar-Free
- Alcohol-Free

Distributed by  
AUROHEALTH LLC  
2572 Brunswick Pike  
Lawrenceville, NJ 08648

Made in India  
Code: TS/DRUGS/19/1 993



LM-3323  
P1033524

AUROHEALTH

## Loratadine Oral Solution USP 5 mg/5 mL Antihistamine

Grape Flavor



AUROHEALTH

NDC 58602-423-11

Ages  
2 years  
and older

\*Compare to the  
active ingredient in  
Children's Claritin®

## Loratadine Oral Solution USP 5 mg/5 mL Antihistamine

### Non-Drowsy\*

#### 24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

### Indoor & Outdoor Allergies

- Dye-Free

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

Dosing Cup Included



\*When taken as directed.  
See Drug Facts Panel.

2 FL OZ (60 mL)

AUROHEALTH

NDC 58602-423-11

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Dosing Cup Included



\*When taken as directed.  
See Drug Facts Panel.

2 FL OZ (60 mL)

LOT  
EXP

N.C.  
Area

## LORATADINE

loratadine oral solution

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58602-423

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		
GRAPE (UNII: 6X543N684K)				
ASCORBIC ACID (UNII: PQ6CK8PD0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
MALTITOL (UNII: D65DG142WK)				
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)				
PHOSPHORIC ACID (UNII: E4GA8884NN)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM METABISULFITE (UNII: 4VON5FNS3C)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	YELLOW (colorless to light yellow)	Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-423-11	1 in 1 CARTON	06/29/2018	
1		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-423-24	1 in 1 CARTON	06/29/2018	
2		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA208931	06/29/2018		

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-423) , MANUFACTURE(58602-423)

Revised: 12/2019

Aurohealth LLC