

LORATADINE - loratadine oral solution
Aurohealth LLC

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

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- Sugar-Free
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Drug Facts

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 (in each 5 mL teaspoonful)
 Loratadine USP, 5 mg..... Antihistamine

Purpose
 Uses temporarily relieves the sea symptoms due to hay fever or other upper respiratory allergies:

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

Warnings
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Directions ■ use only with enclosed dosing cup. adults and children 6 years and over: 2 teaspoonfuls (5p) daily; do not take more than 2 teaspoonfuls (5p) in 24 hours; children 2 to under 6 years of age: 1 teaspoonful (5p) daily; do not take more than 1 teaspoonful (5p) in 24 hours; children under 2 years of age: 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, iron citrate, iron phosphate, iron polyphosphate, phosphoric acid, polyethylene glycol, purified water, sodium benzoate, sodium metabisulfite, sorbitol, sucralose.

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

Distributed by: AUROHEALTH LLC
 2572 Burnside Pk, Lawrenceville, NJ 08648
 Code: TSDRUGS/19/1998 Made in India

LM-324
 1672271J

* 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

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

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:

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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

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Indoor & Outdoor Allergies

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Dosing Cup Included



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2 FL OZ (60 mL)

AUROHEALTH

NDC 58602-423-11

Ages 2 years and older

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

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Non-Drowsy*

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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: 10/2022

Aurohealth LLC