

LORATADINE- loratadine oral solution
BluePoint Laboratories

Loratadine Oral Solution USP 5 mg/5 mL

Drug Facts

Active ingredient (in each 5 mL)

Loratadine USP 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 (1-800-222-1222) right away.

Directions

- use only with enclosed dosing cup
- mL= milliliter

adults and children 6 years and over	10mL daily; do not take more than 10mL in 24 hours
children 2 to under 6 years of age	5mL daily; do not take more than 5mL in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- **each 5mL 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

Manufactured by:

Aurobindo Pharma Limited

Hyderabad-500 090, India

For BluePoint Laboratories

Code:TS/DRUGS/19/1993

Revised: 04/2025

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg/5 mL (120 mL Bottle)

NDC 68001-449-98
Ages 2 years and older
Loratadine
Oral Solution USP
Antihistamine

5 mg/5 mL

Indoor & Outdoor Allergies

Non-Drowsy*
24 Hour Relief of:

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

*When taken as directed.
See Drug Facts Panel.

- Dye-Free
- Sugar-Free
- Alcohol-Free

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

Grape Flavor

4 FL OZ (120 mL)

BluePoint
LABORATORIES

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

Drug Facts

Active Ingredient (in each 5 mL)
Loratadine USP 5 mgAntihistamine

Purpose
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 (1-800-222-1222) right away.

Directions ■ use only with enclosed dosing cup ■ mL = milliliter
adults and children 6 years and over: 10 mL daily, do not take more than 10 mL in 24 hours; children 2 to under 6 years of age: 5 mL daily, do not take more than 5 mL in 24 hours; children under 2 years of age: ask a doctor. Consumers with liver or kidney disease: ask a doctor

Other information ■ each 5 mL 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

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Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 090, India.
For BluePoint Laboratories

Revised: 04/2025

P.14,3,5,9,6,8

Unfinished Zone
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60 x 12 mm

LOT
EXP

NDC 68001-449-98

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

4FL OZ (120 mL)

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

NDC 68001-449-98
Ages 2 years and older
Loratadine
Oral Solution USP
Antihistamine

5 mg/5 mL

Indoor & Outdoor Allergies
Non-Drowsy*

24 Hour Relief of:

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

- Dye-Free
- Sugar-Free
- Alcohol-Free

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

When taken as directed. See Drug Facts Panel.

BluePoint
LABORATORIES

Grape Flavor
4 FL OZ (120 mL)

Drug Facts

Active Ingredient (in each 5 mL teaspoonful)
Loratadine USP 5 mgAntihistamine

Purpose
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

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 090, India
For BluePoint Laboratories

LM-4159

Code: TSDRUGS191988
Issued: 06/2020

P 1426261

LOT
EXP

Unvarnished Zone

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg/5 mL Carton (120 mL)

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

Antihistamine

Grape Flavor

Drug Facts

Active Ingredient (in each 5 mL)	Purpose
Loratadine USP 5 mg	Antihistamine

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

- runny nose
- itchy, watery eyes
- sneezing
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Directions

- use only with enclosed dosing cap
- mL = milliliter

adults and children 6 years and over	10 mL daily; do not take more than 10 mL in 24 hours
children 2 to under 6 years of age	5 mL daily; do not take more than 5 mL in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Drug Facts (continued)

Other information

- each 5 mL 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

*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

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 090, India.
For BluePoint Laboratories

Revised: 04/2025



NDC 68001-449-98

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

Ages 2 years and older

**Loratadine
Oral Solution USP
Antihistamine**

5 mg/5 mL

**Indoor & Outdoor Allergies
Non-Drowsy***

- 24 Hour Relief of:**
- Sneezing
 - Runny Nose
 - Itchy, Watery Eyes
 - Itchy Throat or Nose

- Dye-Free



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

*When taken as directed. See Drug Facts Panel.



NDC 68001-449-98

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

Ages 2 years and older

**Loratadine
Oral Solution USP
Antihistamine**

5 mg/5 mL

**Indoor & Outdoor Allergies
Non-Drowsy***

- 24 Hour Relief of:**
- Sneezing
 - Runny Nose
 - Itchy, Watery Eyes
 - Itchy Throat or Nose

- Dye-Free



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*When taken as directed. See Drug Facts Panel.



P1058707

Unwashed Zone
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47 x 22 mm

Labeling Format Info	
Font type:	Helvetica
Baseline:	Top
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NDC 68001-449-98

#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*
- *Sugar-Free*
- *Alcohol Free*

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

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

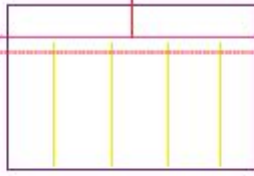
See Drug Facts Panel.

Grape

Flavor

4 FL OZ (120 mL)

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

Grape Flavor

Drug Facts

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

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

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

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Directions

• use only with enclosed dosing cap	
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children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Drug Facts (continued)

Other information

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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

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 090, India
For BluePoint Laboratories
Made in India
Code: TS/DRUGS/19/1993
Issued: 06/2020



LM-4158
P1040925

NDC 68001-449-08

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

**Ages 2 years and older
Loratadine
Oral Solution USP
Antihistamine**

5 mg/5 mL

**Indoor & Outdoor Allergies
Non-Drowsy***

24 Hour Relief of:

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

- Dye-Free

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

Dosing Cup Included



Grape Flavor

*When taken as directed.
See Drug Facts Panel.

BluePoint
LABORATORIES 4 FLOZ (120 mL)

NDC 68001-449-08

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

**Ages 2 years and older
Loratadine
Oral Solution USP
Antihistamine**

5 mg/5 mL

**Indoor & Outdoor Allergies
Non-Drowsy***

24 Hour Relief of:

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

- Dye-Free

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

Dosing Cup Included



Grape Flavor

*When taken as directed.
See Drug Facts Panel.

BluePoint
LABORATORIES 4 FL OZ (120 mL)

LOT
EXP

N.C.
Area

Labeling Form
Font type:
Barcode
Marking

Artwork Colors

LORATADINE
loratadine oral solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-449
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: PDC6A3C00X)	
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:68001-449-98	1 in 1 CARTON	07/31/2020	
1		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	07/31/2020	

Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	analysis(68001-449) , manufacture(68001-449)

Revised: 5/2025

BluePoint Laboratories