LORATADINE- loratadine oral solution
BluePoint Laboratories

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

Manufactured by:

Aurobindo Pharma Limited

Hyderabad-500 090,

India

For BluePoint Laboratories

Made in India

Code:TS/DRUGS/19/1993

Issued: 06/2020

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

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,

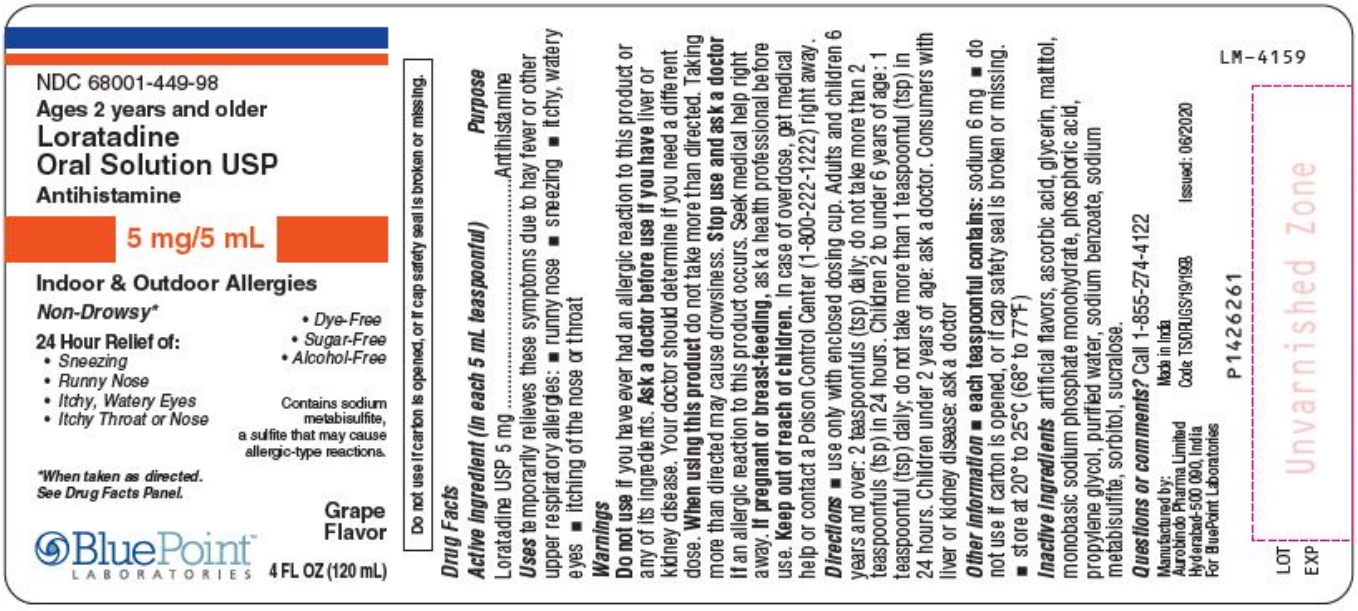
a sulfite that may cause

allergic-type reactions.

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

Grape Flavor

4FL OZ (120 mL)



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

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*

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)

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: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	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: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)