

LORATADINE - loratadine oral solution
Better Living Brands 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?

1-855-274-4122

DISTRIBUTED BY:

BETTER LIVING BRANDS LLC
P.O.BOX 99
PLEASANTON, CA 94566-0009
†1-888-723-3929

Made in India

Code:TS/DRUGS/19/1993

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

NDC 21130-042-24

Signature

care[®]

Quality Guaranteed

Non-Drowsy*

AGES 2 YEARS & OLDER

LORATADINE

ORAL SOLUTION USP

5 mg/5 mL

Antihistamine

24 Hour Relief of:

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

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

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

See Drug Facts Panel.

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


Indoor & Outdoor Allergies

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

GRAPE FLAVOR

4 FL OZ (120 mL)

NDC 21130-042-24



Quality Guaranteed

Non-Drowsy*
AGES 2 YEARS & OLDER

**LORATADINE
ORAL SOLUTION USP
5 mg/5 mL**

Antihistamine

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Indoor & Outdoor Allergies

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- Sugar-Free
- Alcohol-Free

GRAPE FLAVOR 4 FL OZ (120 mL)

Drug Facts

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Purpose
Antihistamine

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

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- 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

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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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DISTRIBUTED BY: BETTER LIVING BRANDS LLC
P.O. BOX 99, PLEASANTON, CA 94566-0009 Made in India
1-888-723-3929 RD 23124 S6657 Code: TS/DRUGS/19/1983



Scan here for more information

LM-5206 P-1432760



* 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 (120 mL)

Compare to
Children's Claritin®
active ingredient

NDC 21130-042-24

**Signature
care®**
Quality Guaranteed

Non-Drowsy*
AGES 2 YEARS & OLDER

**LORATADINE
ORAL SOLUTION
USP 5 mg/5 mL**

Antihistamine

GRAPE FLAVOR

24 Hour Relief of:

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

Indoor & Outdoor Allergies

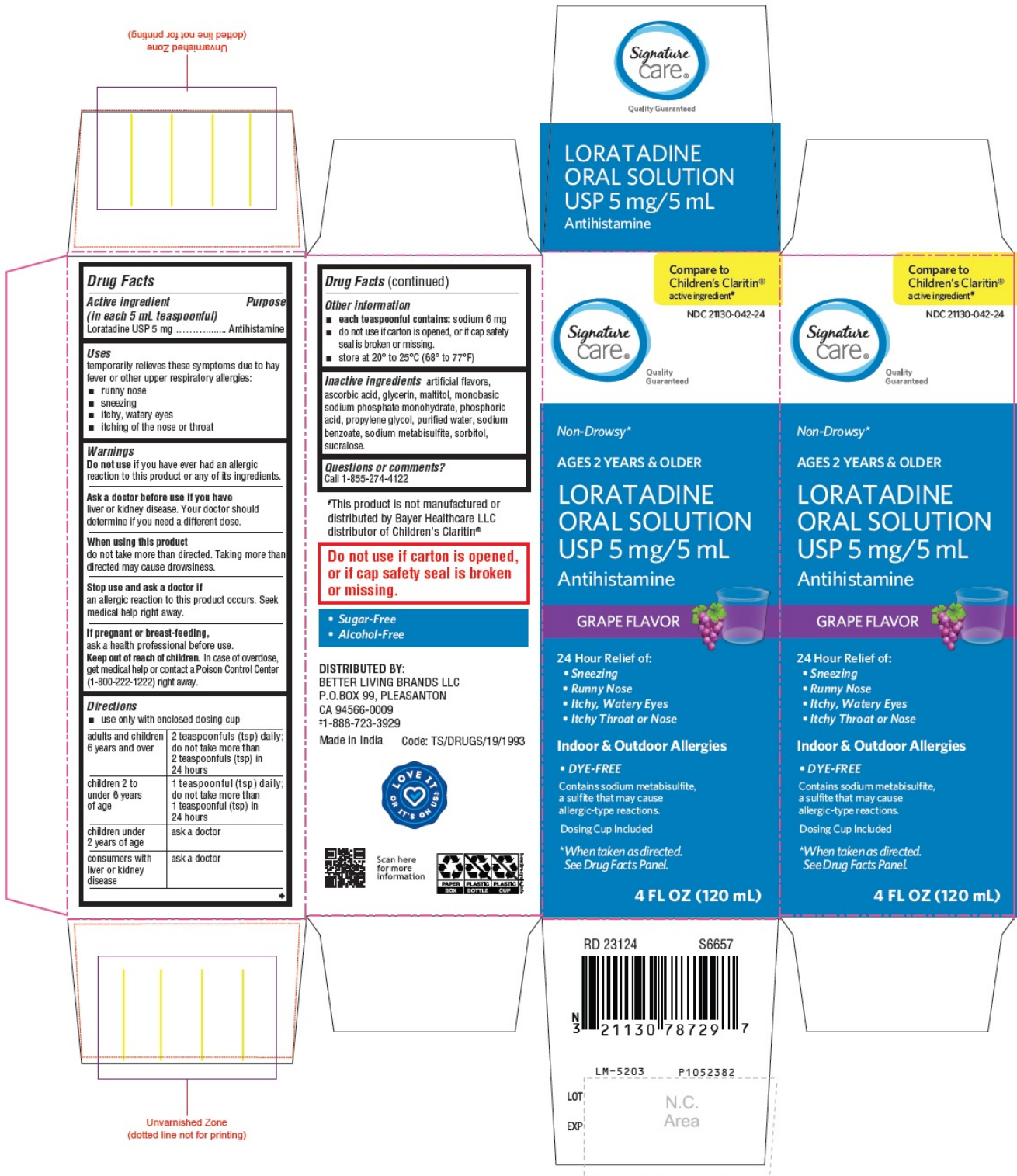
- ***DYE-FREE***

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

Dosing Cup Included

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

4 FL OZ (120 mL)



LORATADINE

loratadine oral solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:21130-042

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:21130-042-24	1 in 1 CARTON	09/25/2023	
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	09/25/2023	

Labeler - Better Living Brands LLC (009137209)**Registrant** - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(21130-042) , MANUFACTURE(21130-042)

Revised: 9/2023

Better Living Brands LLC