**LORATADINE- loratadine oral solution**
**Preferred Pharmaceuticals Inc.**

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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

Manufactured by:

**Aurobindo Pharma Limited**

Hyderabad-500 090,

India

For BluePoint Laboratories

Made in India

Code:TS/DRUGS/19/1993

Issued: 06/2020

**Relabeled By: Preferred Pharmaceuticals Inc.**

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

**NDC 68788-8335-1**
**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,

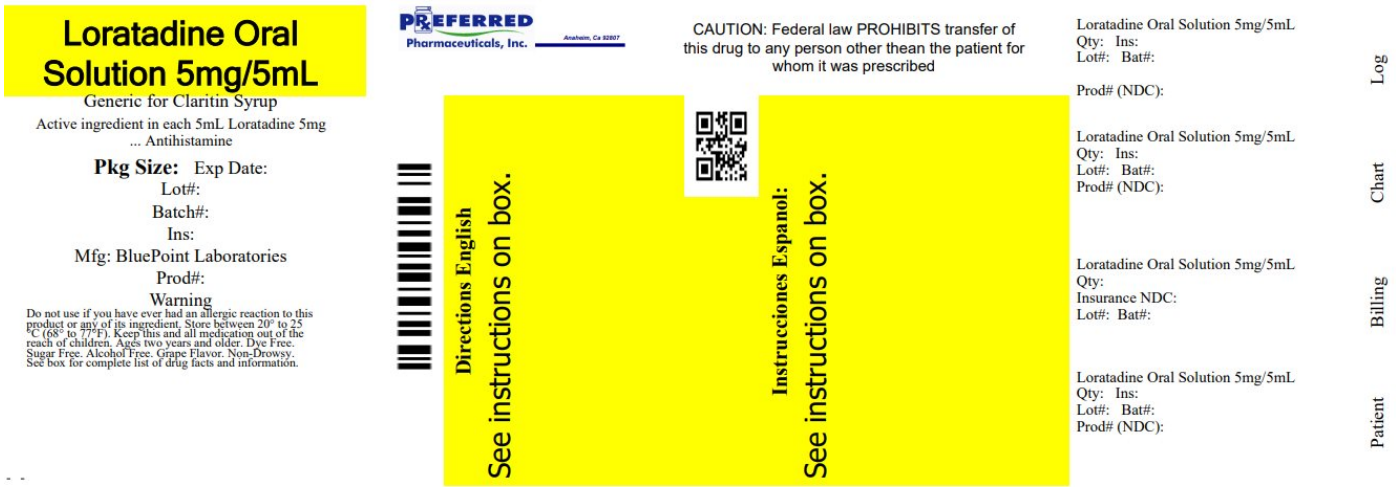
a sulfite that may cause

allergic-type reactions.

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

**Grape Flavor**

**4FL OZ (120 mL)**




# LORATADINE

loratadine oral solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:68788-8335(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:68788-8335-1 | 1 in 1 CARTON | 01/23/2023 | |
| **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 | 01/23/2023 | |

## Labeler - Preferred Pharmaceuticals Inc. (791119022)

## Registrant - Preferred Pharmaceuticals Inc. (791119022)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Preferred Pharmaceuticals Inc. | | 791119022 | RELABEL(68788-8335) |

Revised: 6/2024 Preferred Pharmaceuticals Inc.