

CHILDRENS LORATADINE SUGAR FREE- loratadine solution
Preferred Pharmaceuticals Inc.

Childrens Loratadine Oral Solution
Sugar Free

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

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

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

- **do not use if bottle wrap imprinted with "SEALED FOR SAFETY" is broken or missing.**
- see bottom panel for lot number and expiration date
- store between 20° and 25°C (68° and 77°F)

Inactive ingredients

butylated hydroxyanisole, glycerin, grape flavor, maltitol solution, masking agent, phosphoric acid, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium phosphate monobasic dihydrate, sorbitol solution, sucralose powder.

Questions?

Call **1-866-923-4914**

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

Relabeled By: Preferred Pharmaceuticals Inc.

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 68788-8286-1

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

Original Prescription Strength

Children's

Loratadine

Oral Solution

USP, 5 mg/5 mL

(Antihistamine) **ALLERGY**

Non-Drowsy[†]

Indoor & Outdoor Allergies

SUGAR FREE

24

Hour

Relief of:

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

Ages 2 years and older


Dosing Cup

Enclosed

**Grape
Flavor**

†When taken as directed.
See Drug Facts Panel.

4 FL OZ
(120 mL)

<p>Loratadine Oral Solution USP 5mg /5mL</p> <p>Generic for Claritin Syrup Active ingredient in each 5mL Loratadine 5mg ... Antihistamine</p> <p>Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: Taro Pharmaceuticals U.S.A., Inc. Prod#: Warning</p> <p><small>Do not use if you have ever had an allergic reaction to this product or any of its ingredients. Store between 20° to 25° C (68° to 77°F). Keep this and all medication out of the reach of children. Ages two years and older. Dye Free. Sugar Free, Grape Flavor, Non-Drowsy. See box for complete list of drug facts and information.</small></p>	 <p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p>	<p>Loratadine Oral Solution USP 5mg/5mL Qty: Ins: Lot#: Bat#:</p> <p>Prod# (NDC):</p> <p>Loratadine Oral Solution USP 5mg/5mL Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>Loratadine Oral Solution USP 5mg/5mL Qty: Insurance NDC: Lot#: Bat#:</p> <p>Loratadine Oral Solution USP 5mg/5mL Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	<p>Log</p> <p>Chart</p> <p>Billing</p> <p>Patient</p>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Directions English See instructions on box.</p>		<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Instrucciones Espanol: See instructions on box.</p>	

CHILDRENS LORATADINE SUGAR FREE			
loratadine solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8286(NDC:51672-2131)
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
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	

Product Characteristics

Color	YELLOW (colorless to slightly yellow)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8286-1	1 in 1 CARTON	11/29/2022	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076805	11/29/2022	

Labeler - Preferred Pharmaceuticals Inc. (791119022)**Registrant** - Preferred Pharmaceuticals Inc. (791119022)**Establishment**

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Revised: 7/2023

Preferred Pharmaceuticals Inc.