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

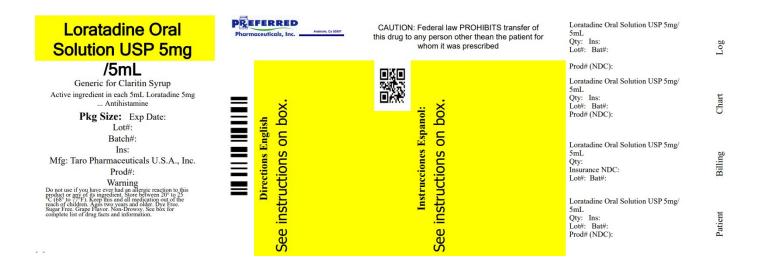
Ages 2 years and older

Dosing Cup Enclosed

Grape Flavor

[†]When taken as directed. See Drug Facts Panel.

4 FL OZ (120 mL)



CHILDRENS LORATADINE SUGAR FREE Interstation Interstation Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68788-8286(NDC:51672-2131) Route of Administration ORAL Item Code (Source) NDC:68788-8286(NDC:51672-2131)

Active ingred	lient/Active Moiety	Pacie of Strongt	h Stuanath				
Ingredient Name oratadine (UNII: 7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN)		Basis of Strengt	h Strength 5 mg in 5 ml				
		Loratadine	5 mg m 5 m				
nactive Ingr	edients						
Ingredient Name							
UTYLATED HYD	ROXYANISOLE (UNII: REK4960K2U)						
GLYCERIN (UNII: PDC6A3C0OX)							
ORBITOL (UNII: 5							
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)							
PHOSPHORIC ACID (UNII: E4GA8884NN)							
	COL (UNII: 6DC9Q167V3)						
VATER (UNII: 059							
	TE (UNII: OJ245FE5EU)						
SODIUM PHOSPH	ATE, MONOBASIC, DIHYDRATE (UNII: 5QWK66595	6)					
Product Char							
Color	YELLOW (colorless to slightly yellow) Score						
Shape		Size					
lavor	GRAPE	Imprint Cod	e				
Contains							
Packaging							
# Item Code	Package Description	Marketing Start M Date	Marketing End Date				
NDC:68788- 8286-1	1 in 1 CARTON	11/29/2022					
L	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				
NDA	ANDA076805	11/29/2022					

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment			
Name	Address	ID/FEI	Business Operations

Revised: 7/2023

Preferred Pharmaceuticals Inc.