CHILDRENS LORATADINE SUGAR FREE- loratadine solution
Taro Pharmaceuticals U.S.A., 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	2 teaspoonfuls (tsp) daily; do not take

adults and children 6 years and over	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

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 51672-2131-8

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)

NDC 51672-2131-8

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

Children's

Loratadine Oral Solution USP, 5 mg/5 mL

(Antihistamine) ALLERGY

Non-Drowsy†

Indoor & Outdoor Allergies

NDC 51672-2131-8

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

4 FL OZ

†When taken as directed.

Original Prescription Strength

Children's

Loratadine Oral Solution USP, 5 mg/5 mL

(Antihistamine) ALLERGY

Non-Drowsy†

Indoor & Outdoor Allergies

- Alcohol Free
- Sugar Free
- 24 Hour Relief
- Dye Free

Dosing Cup Enclosed

Grape Flavor

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Children's Claritin®.

Distributed by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532
TARO is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.

See Drug Facts Panel. (120 mL)

TARO Made in Canada

NO COPY ON THIS FLAP FOR LOT # AND EXPIRY DATE PRINT

T181C

N 3 51672 21318 3

NO VARNISH ON THIS FLAP

NDC 51672-2131-8

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

SEALED WITH PRINTED NECKBAND

Drug Facts

Active Ingredient (In each 5 mL teaspoonful)	Purpose
Loratadine 5 mg	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

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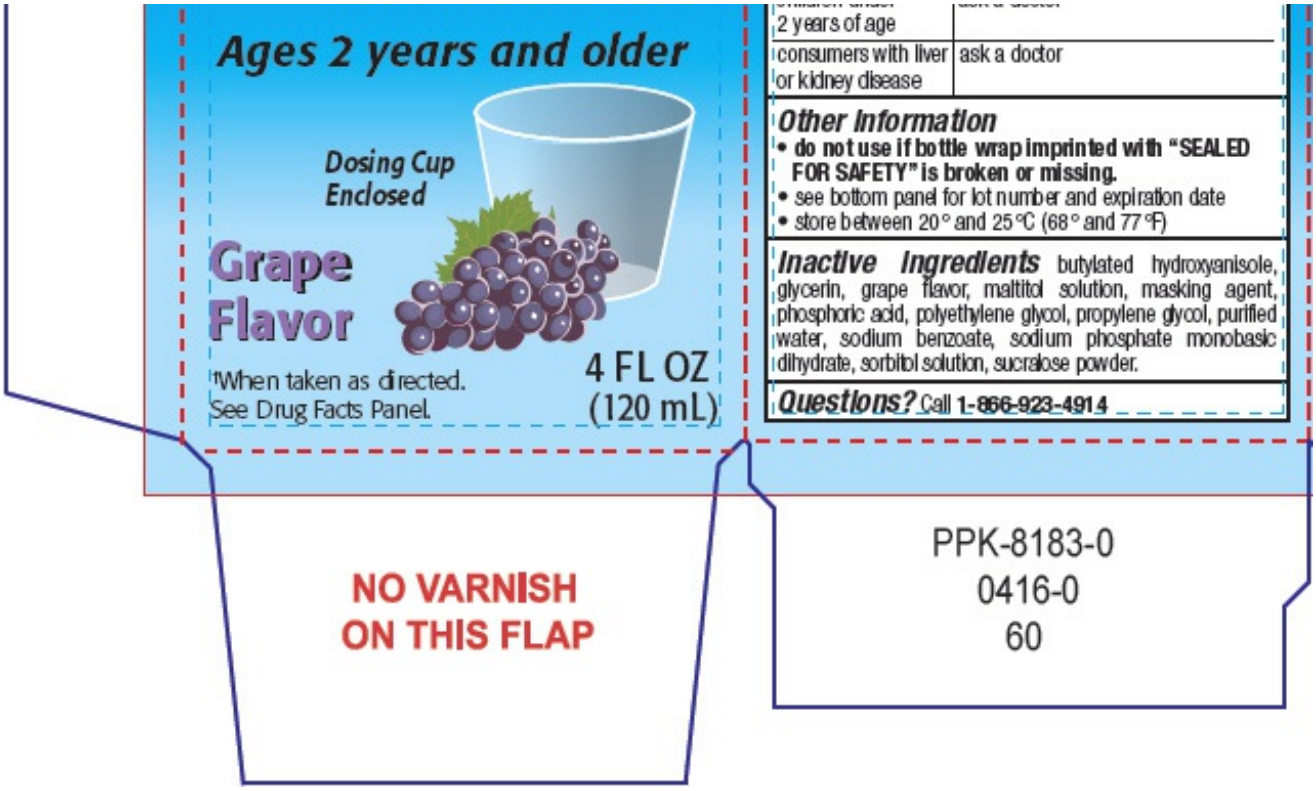
Directions • use only with enclosed dosing cup

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	ask a doctor



CHILDRENS LORATADINE SUGAR FREE

loratadine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2131
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**
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MALTITOL (UNII: D65DG142WK)	

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:51672-2131-4	1 in 1 CARTON	03/17/2017	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2131-8	1 in 1 CARTON	03/17/2017	
2		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51672-2131-1	1 in 1 CARTON	03/17/2017	
3		240 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	03/17/2017	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2131)

Revised: 8/2023 Taro Pharmaceuticals U.S.A., Inc.