CHILDRENS LORATADINE SUGAR FREE- loratadine solution
Taro Pharmaceuticals U.S.A., Inc.

Children's 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

adults and children 6 years and over	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 5 mg
- **do not use if bottle wrap imprinted with "SEALED FOR SAFETY" is broken or missing.**
- store between 20° and 25°C (68° and 77°F)
- see bottom panel for lot number and expiration date

Inactive ingredients

bubble gum flavor, butylated hydroxyanisole, glycerin, maltitol solution, noncrystallizing sorbitol solution, phosphoric acid, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium phosphate monobasic dihydrate, 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

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

NDC 51672-2108-8

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

Bubble Gum
Flavor

†When taken as directed.
See Drug Facts Panel.

4 FL OZ
(120 mL)

NDC 51672-2108-8

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

SUGAR FREE

24 Hour Relief of:

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

Ages 2 years and older

Dosing Cup Enclosed

Bubble Gum Flavor

4 FL OZ

NDC 51672-2108-8

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

Children's Loratadine Oral Solution USP, 5 mg/5 mL

(Antihistamine) ALLERGY

Indoor & Outdoor Allergies

NDC 51672-2108-8

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

SUGAR FREE

24 Hour Relief of:

- Sneezing
- Runny Nose
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Ages 2 years and older

Dosing Cup Enclosed

Bubble Gum Flavor

4 FL OZ

When taken as directed.
See Drug Facts Panel.
(120 mL)

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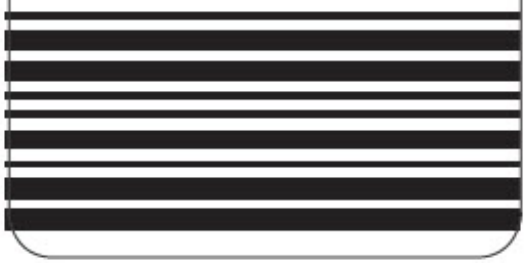

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Drug Facts

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

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

Drug Facts (continued)

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 5 mg
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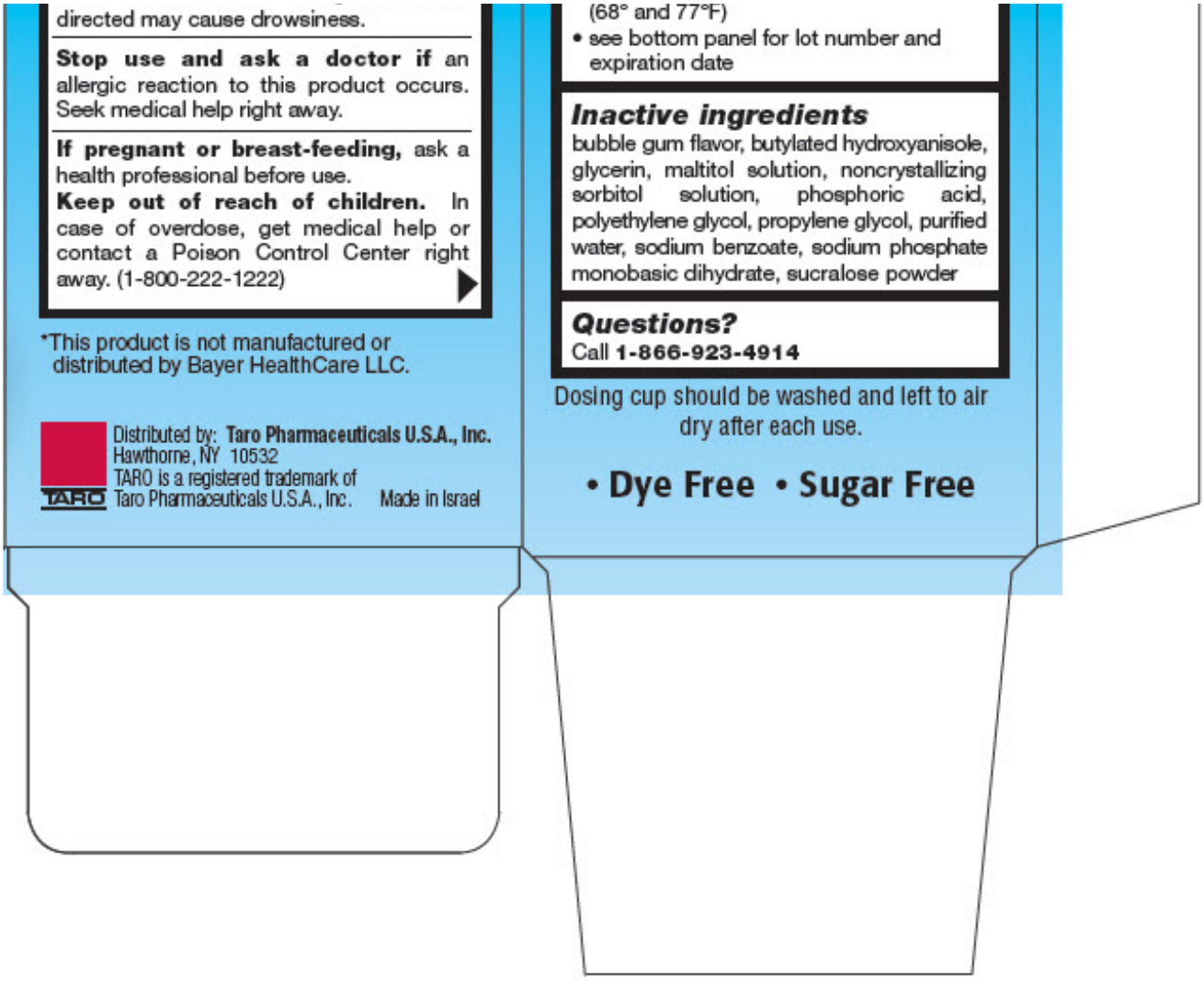

CHILDRENS LORATADINE SUGAR FREE

loratadine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2108
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)	
polyethylene glycol, unspecified (UNII: 3WQ0SDW1A)	
sorbitol (UNII: 506T60A25R)	

phosphoric acid (UNII: E4GA8884NN)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium phosphate, monobasic, dihydrate (UNII: 5QWK665956)	

Product Characteristics

Color	YELLOW (colorless to slightly yellow)	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2108-8	1 in 1 CARTON	12/08/2016	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2108-1	1 in 1 CARTON	12/08/2016	
2		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	ANDA201865	12/08/2016	

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(51672-2108)

Revised: 4/2021 Taro Pharmaceuticals U.S.A., Inc.