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

Children's Loratadine

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	ask a doctor

disease

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

glycerin, grape flavor, maltitol solution, masking agent, noncrystallizing sorbitol solution, phosphoric acid, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, 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

NDC 51672-2092-8

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†

24 Hour
Relief of:

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

Indoor & Outdoor Allergies
Ages 2 years and older

WARNING: Contains sodium metabisulfite,
a sulfite that may cause allergic-type reactions.

Dye Free

Sugar Free
Grape
Flavor

Dosage Cup
Enclosed

†When taken as directed.
See Drug Facts Panel.

4 FL OZ
(120 mL)

CHILDRENS LORATADINE

loratadine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2092
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**
glycerin (UNII: PDC6A3C0OX)	
sorbitol (UNII: 506T60A25R)	
phosphoric acid (UNII: E4GA8884NN)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
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:51672-2092-4	1 in 1 CARTON	02/27/2010	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2092-8	1 in 1 CARTON	02/27/2010	
2		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51672-2092-1	1 in 1 CARTON	02/27/2010	
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	02/27/2010	

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2092)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(51672-2092)

Revised: 1/2020 Taro Pharmaceuticals U.S.A., Inc.