

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

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**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 disease	ask a doctor

**Other information**

- do not use if carton is opened, or if imprinted safety seal is broken or missing
- see bottom panel for expiration date
- store between 20° to 25°C (68° to 77°F)

**Inactive ingredients**

artificial grape flavor, citric acid monohydrate, glycerin, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sucrose

**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 xxxxx-xxxx-x

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

**GRAPE  
FLAVOR**

Original  
Prescription Strength

Ages two years and older

Children's  
**Loratadine**

**Syrup**  
*(Loratadine  
Oral Solution)*

**5 mg/5 mL**  
**Antihistamine**

**Grape Flavored Syrup**

**24 Hour Non-Drowsy†**  
**Allergy Relief**

**Indoor &  
Outdoor  
Allergies**

**Relief of:**  
*Sneezing; Runny Nose,  
Itchy, Watery Eyes,  
Itchy Throat or Nose*

**4 FL OZ (120 mL)**

† When taken as directed. See Drug Facts Panel.



## CHILDRENS LORATADINE

loratadine solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2085
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
citric acid monohydrate (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium metabisulfite (UNII: 4VON5FNS3C)	
sucrose (UNII: C151H8M554)	

**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:51672-2085-8	1 in 1 CARTON	08/20/2004	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2085-4	1 in 1 CARTON	08/20/2004	
2		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51672-2085-5	1 in 1 CARTON	08/20/2004	
3		180 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:51672-2085-1	1 in 1 CARTON	08/20/2004	
4		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	08/20/2004	

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

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(51672-2085)

