

**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 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**

artificial peach 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 51672-2073-8

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  
Fruit Flavor**

**Dosage Cup  
Enclosed**

†When taken as directed.  
See Drug Facts Panel.

**4 FL OZ  
(120 mL)**

	<p>NDC 51672-2073-8 Compare to the active ingredient in Children's Claritin*</p> <p><b>Children's</b> <b>Loratadine Oral Solution USP, 5 mg/5 mL</b> <i>(Antihistamine)</i> <b>ALLERGY</b></p>	<p>08E 90314-0915-5</p>													
<p><b>SEALED WITH PRINTED NECKBAND</b></p> <p><b>Drug Facts</b></p> <table border="1"> <tr> <th>Active ingredient (in each 5 mL teaspoonful)</th> <th>Purpose</th> </tr> <tr> <td>Loratadine 5 mg.....</td> <td>Antihistamine</td> </tr> </table> <p><b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> <li>• runny nose</li> <li>• sneezing</li> <li>• itchy, watery eyes</li> <li>• itching of the nose or throat</li> </ul> <p><b>Warnings</b> 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)</p> <p><b>Directions</b> • use only with enclosed dosing cup</p> <table border="1"> <tr> <td>adults and children 6 years and over</td> <td>2 teaspoonfuls (tsp) daily; do not take more than 2 teaspoonfuls (tsp) in 24 hours</td> </tr> <tr> <td>children 2 to under 6 years of age</td> <td>1 teaspoonful (tsp) daily; do not take more than 1 teaspoonful (tsp) in 24 hours</td> </tr> <tr> <td>children under 2 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table> <p><b>Other information</b> • 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)</p> <p><b>Inactive ingredients</b> artificial peach flavor, citric acid monohydrate, glycerin, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sucrose</p> <p><b>Questions?</b> Call 1-866-923-4914</p>	Active ingredient (in each 5 mL teaspoonful)	Purpose	Loratadine 5 mg.....	Antihistamine	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	<p>NDC 51672-2073-8 Compare to the active ingredient in Children's Claritin*</p> <p><b>Original Prescription Strength</b> <b>Children's</b> <b>Loratadine Oral Solution USP, 5 mg/5 mL</b> <i>(Antihistamine)</i> <b>ALLERGY</b> <b>Non-Drowsy†</b> <b>24 Hour Relief of:</b></p> <ul style="list-style-type: none"> <li>• Sneezing</li> <li>• Runny Nose</li> <li>• Itchy, Watery Eyes</li> <li>• Itchy Throat or Nose</li> </ul> <p><b>Indoor &amp; Outdoor Allergies</b> <b>Ages 2 years and older</b> <b>WARNING:</b> Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.</p>	<p>NDC 51672-2073-8 Compare to the active ingredient in Children's Claritin*</p> <p><b>Original Prescription Strength</b> <b>Children's</b> <b>Loratadine Oral Solution USP, 5 mg/5 mL</b> <i>(Antihistamine)</i> <b>ALLERGY</b> <b>Indoor &amp; Outdoor Allergies</b></p> <ul style="list-style-type: none"> <li>• Alcohol Free</li> <li>• 24 Hour Relief</li> <li>• Dye Free</li> </ul>  <p><i>Dosage Cup Enclosed</i></p> <p>* This product is not manufactured or distributed by MSD Consumer Care Inc., a subsidiary of Merck &amp; Co., Inc.</p> <p>Distributed by: <b>TARO Pharmaceuticals U.S.A., Inc.</b> Hawthorne, NY 10532 TARO is a registered trademark of Taro Pharmaceuticals U.S.A., Inc. Made in Israel</p>	<p>NDC 51672-2073-8 Compare to the active ingredient in Children's Claritin*</p> <p><b>Original Prescription Strength</b> <b>Children's</b> <b>Loratadine Oral Solution USP, 5 mg/5 mL</b> <i>(Antihistamine)</i> <b>ALLERGY</b> <b>Non-Drowsy†</b> <b>24 Hour Relief of:</b></p> <ul style="list-style-type: none"> <li>• Sneezing</li> <li>• Runny Nose</li> <li>• Itchy, Watery Eyes</li> <li>• Itchy Throat or Nose</li> </ul> <p><b>Indoor &amp; Outdoor Allergies</b> <b>Ages 2 years and older</b> <b>WARNING:</b> Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.</p>
Active ingredient (in each 5 mL teaspoonful)	Purpose														
Loratadine 5 mg.....	Antihistamine														
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														
 <p>3 51672 20738 0</p>	<p><b>Dye Free</b> <b>Fruit Flavor</b></p>  <p><i>Dosage Cup Enclosed</i></p> <p><b>4 FL OZ (120 mL)</b></p> <p>When taken as directed. See Drug Facts Panel.</p>	<p><b>Dye Free</b> <b>Fruit Flavor</b></p>  <p><i>Dosage Cup Enclosed</i></p> <p><b>4 FL OZ (120 mL)</b></p> <p>When taken as directed. See Drug Facts Panel.</p>													

# CHILDRENS LORATADINE

loratadine solution

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2073
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	FRUIT (peach)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2073-8	1 in 1 CARTON	08/20/2004	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2073-4	1 in 1 CARTON	08/20/2004	
2		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51672-2073-5	1 in 1 CARTON	08/20/2004	
3		180 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(51672-2073)

Revised: 1/2020

Taro Pharmaceuticals U.S.A., Inc.