

**LORATADINE- loratadine solution**  
**Cardinal Health, 110 dba LEADER**

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**Children's Allergy Loratadine Oral Solution**

***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

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adults and children 6 years and over | 2 teaspoonfuls (tsp) daily; do not take more than 2

years and over	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 CARDINAL HEALTH  
DUBLIN, OHIO 43017

### PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

**LEADER™**

**Non-Drowsy†  
Children's  
Allergy**

**Loratadine Oral Solution  
USP, 5 mg/5 mL**

**Antihistamine Allergy  
Indoor & Outdoor Allergies**

**Fruit** Flavor  
Dye Free

**24 Hour  
Relief of:**

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

**Ages 2 Years  
and Older**

**COMPARE TO  
CHILDREN'S  
CLARITIN®**

active ingredient\*

100% Money  
Back Guarantee

†When taken as directed. See Drug Facts Panel.

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

**4 FL OZ (118 mL)**

**LEADER** 

**LEADER** 



Use only with enclosed dosing cup.  
Wash and let air dry after each use.

\*This product is not manufactured or distributed by MSD Consumer Care Inc., a subsidiary of Merck & Co., Inc.

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DUBLIN, OHIO 43017  
www.myleader.com 1-800-200-6313  
**Essential to Care™ since 1979**  
MADE IN ISRAEL



All LEADER® Brand Products Have A  
**100% Money Back Guarantee**

Non-Drowsy\*

**Children's**

# Allergy

**Loratadine Oral Solution**

**USP, 5 mg/5 mL**

**Antihistamine Allergy**

**Indoor & Outdoor Allergies**

**Fruit** Flavor

Dye Free

**24 Hour  
Relief of:**

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active ingredient\***

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4 FL OZ (118 mL)

Return to place of purchase if not satisfied.

4 FL OZ (118 mL)

70506-1016-3  
478

LEADER<sup>2</sup>

Children's  
**Allergy**

Loratadine Oral Solution  
USP, 5 mg/5 mL  
Antihistamine Allergy

Fruit<sup>Flavor</sup>  
Dye Free

LEADER<sup>2</sup>

NDC 70000-0125-1

Non-Drowsy<sup>†</sup>

Children's  
**Allergy**

Loratadine Oral Solution  
USP, 5 mg/5 mL  
Antihistamine Allergy

SEALED WITH PRINTED NECKBAND

**Drug Facts**

Active ingredient (in each 5 mL teaspoonful)	Purpose
Loratadine 5 mg.....	Antihistamine

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- runny nose
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(1-800-222-1222)

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**Indoor & Outdoor Allergies**



**Fruit** Flavor  
Dye Free

**24 Hour Relief of:**

- Sneezing
- Runny Nose
- Itchy Watery Eyes
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**Ages 2 Years and Older**

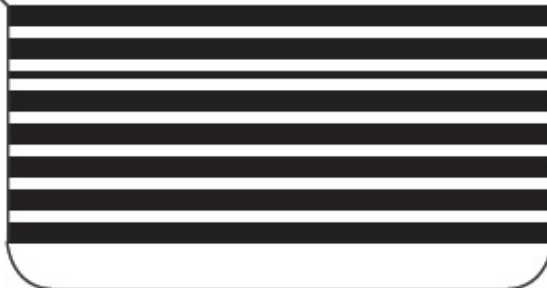
**COMPARE TO CHILDREN'S CLARITIN®**  
active ingredient\*

**100% Money Back Guarantee**

\*When taken as directed. See Drug Facts Panel.

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

**4 FL OZ (118 mL)**



CIN 5279609 REV. 10/16



**LORATADINE**

loratadine solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0125
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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<b>Loratadine</b> (UNII: 7AJ03BO7QN) (Loratadine - UNII:7AJ03BO7QN)	Loratadine	5 mg in 5 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>citric acid monohydrate</b> (UNII: 2968PHW8QP)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>sodium metabisulfite</b> (UNII: 4VON5FNS3C)	
<b>sucrose</b> (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	YELLOW (colorless to slightly yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0125-1	1 in 1 CARTON	10/24/2016	
1		118 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** - Cardinal Health, 110 dba LEADER (063997360)

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