

**CHILDRENS ALLERGY RELIEF- loratadine solution**  
CVS Pharmacy

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**Children's  
Allergy**

***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

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: CVS Pharmacy, Inc.**  
One CVS Drive, Woonsocket, RI 02895

### PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

CVS  
Health™

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

**Indoor & Outdoor  
Allergies**

NDC 59779-093-08

**Children's  
Allergy**

**24  
HOUR**

**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**
- **Sugar free & Dye free**
- **Ages 2 yrs & older**

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

\*When taken as directed.

See Drug Facts Panel.

**Grape Flavor**

Dosing Cup Enclosed

**4 FL OZ (120 mL)**



Indoor & Outdoor Allergies

# Children's Allergy

## LORATADINE

ORAL SOLUTION  
USP, 5 mg/5 mL  
(Antihistamine)  
ALLERGY



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

Indoor & Outdoor Allergies

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Grape Flavor  
Dosing Cup Enclosed

4 FL OZ (120 mL)

NO VARNISH/ NO AQ  
NO COPY / NO COLOR  
THIS FLAP FOR LOT #  
AND EXP DATE PRINT

Grape Flavor  
Dosing Cup Enclosed

4 FL OZ (120 mL)

T181C  
B98.2  
ENG19.59



NO VARNISH  
ON THIS FLAP

**Children's**  
**Allergy**  
**LORATADINE**

ORAL SOLUTION  
USP, 5 mg/5 mL  
(Antihistamine)  
ALLERGY



Non-Drowsy\*

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

Dosing Cup  
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Dosing cup should be

SEALED WITH PRINTED NECKBAND

**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:

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**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get

Dosing cup should be washed and left to air dry after each use.

This product is not manufactured or distributed by MSD Consumer Care Inc., owner of the registered trademark Claritin®.

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Made in Canada  
 V-16793



#912845



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**Questions?** Call 1-866-923-4914

NO VARNISH  
ON THIS FLAP

PPK-7864-2  
1215-2  
M215

**CHILDRENS ALLERGY RELIEF**

loratadine solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-093
<b>Route of Administration</b>	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
glycerin (UNII: PDC6A3C0OX)	

sorbitol (UNII: 506T60A25R)	
phosphoric acid (UNII: E4GA8884NN)	
polyethylene glycols (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:59779-093-04	1 in 1 CARTON		
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59779-093-01	1 in 1 CARTON		
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59779-093-08	1 in 1 CARTON		
3		120 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** - CVS Pharmacy (062312574)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(59779-093)

### Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(59779-093)