# PREMIER VALUE CHILDRENS LORATADINE- loratadine solution Chain Drug Constortium

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Premier Value 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	2 teaspoonfuls (tsp) daily; do not take more than 2	
and over	teaspoonfuls (tsp) in 24 hours	
children 2 to under 6 years	1 teaspoonful (tsp) daily; do not take more than 1	
of age	teaspoonful (tsp) in 24 hours	
children under 2 years of	ask a doctor	
age	ask a doctor	
consumers with liver or kidney disease	ask a doctor	

### Other information

- safety sealed: do not use if imprinted safety seal is torn or missing
- 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 CHAIN DRUG CONSORTIUM 3301 NW BOCA RATON BLVD SUITE 101, BOCA RATON, FL 33431

### PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 68016-164-01

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S CLARITIN®\*

**Premier** 

Value

Ages

two years

and older

Children's

Loratadine

**Oral Solution** 

5 mg/5 mL

Antihistamine

## **SUGAR FREE**

**GRAPE** flavor

Non-Drowsy<sup>†</sup>

24 hour Allergy

Relief of: Sneezing;

Runny Nose; Itchy, Watery Eyes;

Itchy Throat or Nose

# INDOOR & OUTDOOR

**ALLERGIES** 

<sup>†</sup>When taken as directed. See Drug Facts Panel.

### INDEPENDENTLY TESTED

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# SATISFACTION GUARANTEED

4 FL OZ (120 mL)





NOC 68016-164-01 Compare to the Active inspedient in Children's Clariting

Ages two years and older

Children's

# Loratadine

Oral Solution 5 mg/5 mL

Antihistamine

# SUGAR FREE GRAPE flavor

Non-Drowsy<sup>†</sup>

24 hour Allergy Relief of: Sneezing;

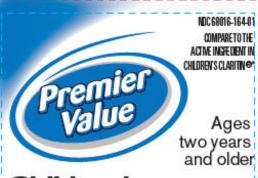
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INDOOR & OUTDOOR ALLERGIES

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4 FL OZ (120 ml)





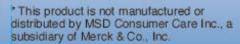
# Children's

# Loratadine

Oral Solution 5 mg/5 mL

Antihistamine

- Alcohol Free
- Sugar Free
- 24 Hour Relief
- Grape Flavored
- Dosage Cup Enclosed



DISTRIBUTED BY CHAIN DRUG CONSORTIUM 3301 NW BOCA RATON BLVD SUITE 101, BOCA RATON, FL 33431 Made in Canada

If for any reason you are not satisfied with this product, please return it to the store where purchased





# T181C



NO VARNISH ON THIS FLAP



NDC 68016-164-01 COMPARETOTHE ACTIVE INGREDIENT IN CHILDREN'S CLARITING

Ages two years

# Children's

# Loratadine

Oral Solution 5 mg/5 mL

Antihistamine

# SUGAR FREE GRAPE flavor

Non-Drowsy<sup>†</sup>

24 hour Alleray

# 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:

- · runny nose
- itchy, watery eyes
   itching of the nose or throat
- · sneezing

### Warnings

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## 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 more than 1 teaspoonful (tsp) daily; do not take more than 1 teaspoonful (tsp) in 24 hours children under 2 years of age ask a doctor or kidney disease

Other Information • safety sealed: do not use if imprinted safety seal is torn or missing

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Inactive Ingredients glycerin, grape flavor, maltitud 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

NO VARNISH ON THIS FLAP PPK-7093-1 0913-1 M168

# PREMIER VALUE CHILDRENS LORATADINE

loratadine solution

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-164

Route of Administration ORAL

### Active Ingredient/Active Moiety

П	· · · · · · · · · · · · · · · · · · ·		
	Ingredient Name	Basis of Strength	Strength
	Loratadine (UNII: 7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN)	Loratadine	5 mg in 5 mL

# 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 phosphate, monobasic, dihydrate (UNII: 5QWK665956)

Product Characteristics			
Color	YELLOW (colorless to slightly yellow)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-164-01	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076805	02/27/2010	

# Labeler - Chain Drug Constortium (101668460)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(68016-164)

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(68016-164)	

Revised: 3/2014 Chain Drug Constortium