PREMIER VALUE CHILDRENS LORATADINE- loratadine solution Chain Drug Constortium

Premier Value Childrens 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	
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cimuren under ∠ years of age	ask a doctor
consumers with liver or kidney	ask a doctor
disease	

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

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

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 68016-085-08

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

GRAPE flavor

Non-Drowsy[†]

24 hour Allergy

Relief of: Sneezing;

Runny Nose; Itchy, Watery Eyes;

Itchy Throat or Nose

INDOOR & OUTDOOR ALLERGIES

 $^{\dagger}When\,taken\,as\,directed.$ See Drug Facts Panel. INDEPENDENTLY TESTED

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SATISFACTION GUARANTEED

4 FL OZ (120 mL)



999 70282-1211-1

SEALED WITH PRINTED NECKBAND

Drug Facts

Active ingredient

(in each 5 mL teaspoonful)
Lo atadine 5 mg.....

Purpose

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

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 kichey 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.

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adults and children 6 years and over	2 teaspoonfuls (TSP) daily; do not take more than 2 teaspoonfuls
6 years and over	(TSP) in 24 hours
childnen 2 to under 6 years of a ge	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

- 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 artificial grape flavor, citric acid monohydrate, glycarin, propylene glycol, purified water, sod ium benzoate, sod ium metabisulfile, sucrose

Questions? Call 1-966-923-4914



NDC64016JD45JD4 COMPARETO THE ACTIVE INGREDIBITIN HUDBEN SCI VELLING

Ages two years and older

Children's Loratadine

Oral Solution 5 mg/5 mL

Antihistamine

GRAPE flavor

Non-Drowsy[†] 24 hour Allergy Relief of: Sneezing;

Runny Nose; Itchy, Watery Eyes; Itchy Throat or Nose

INDOOR & OUTDOOR ALLERGIES

tWhen taken as directed. See Drug Facts Panel.

4 FL OZ (120 mL)





NIC BAD 16-DAS-DA COMPANETOTHE Active ingredient in Children's Claritin &

Ages two years and older

Children's Loratadine Oral Solution 5 mg/5 mL

Antihistamine

- 24 Hour Relief
- Alcohol Free
- · Gluten Free
- Dye Free
- · Grape Flavored

Dosage Cup Enclosed

"This product is not manufactured or distributed by Schering-Plough HealthCare Products Inc., owner of the registered trademark Children's Claritin*

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



NID CROOM BURBLUR COMPARE TO THE ACTIVE INGREDIENT IN CHLOR INS CLARITIVE

Ages two years and older

Children's Loratadine Oral Solution

5 mg/5 mL Antihistamine

GRAPE flavor

Non-Drowsy[†] 24 hour Allergy Relief of: Sneezing: Runny Nose; Itchy, Watery Eyes; Itchy Throat or Nose

INDOOR & OUTDOOR ALLERGIES

†When taken as directed. See Drug Facts Panel.

4 FL OZ (120 mL)





PREMIER VALUE CHILDRENS LORATADINE

loratadine solution

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HUMAN OTC DRUG NDC:68016-085 Product Type Item Code (Source)

Route of Administration

ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Loratadine (UNII: 7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN)	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: C151H8 M554)	

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:68016-085-08	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	08/20/2004	

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(68016-085)	

Revised: 10/2012 Chain Drug Constortium