

QUALITY CHOICE CHILDRENS ALLERGY RELIEF- loratadine solution
Chain Drug Marketing Association, Inc.

Quality Choice
Children's Allergy Relief

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

- **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 **248-449-9300**

Distributed by C.D.M.A., Inc.

43157 W. Nine Mile
Novi, MI 48376-0995

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 63868-092-08

**QC
QUALITY
CHOICE®**

**Compare to the
active ingredient in
Children's CLARITIN®***

children's
**Allergy
Relief**

Loratadine
Oral Solution 5 mg/5 mL
Antihistamine

**Indoor & Outdoor
Allergies**

**24 Hour Non-Drowsy^t
Allergy Relief of:**

Runny Nose | Sneezing
Itchy, watery eyes
Itchy throat or nose

Dosing Cup
Included

2 Yrs. & older

**Sugar Free
Grape**

Flavor

†When taken as directed.

See Drug Facts Panel

4 FL OZ (120 mL)

NO VARNISH ON THIS FLAP

QC QUALITY CHOICE NDC 63868-092-08

Compare to the active ingredient in Children's CLARITIN®

children's Allergy Relief

Loratadine Oral Solution 5 mg/5 mL Antihistamine

Indoor & Outdoor Allergies

24 Hour Non-Drowsy† Allergy Relief of:
Runny Nose | Sneezing
Itchy, watery eyes
Itchy throat or nose

2 Yrs. & older
Sugar Free
Grape Flavor

Dosing Cup Included

4 FL OZ (120 mL)

NO VARNISH ON THIS FLAP

PPK-7095-1
0913-1
M171

QC QUALITY CHOICE NDC 63868-092-08

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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
• sneezing • itching of the nose or throat

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QC QUALITY CHOICE NDC 63868-092-08

Compare to the active ingredient in Children's CLARITIN®

children's Allergy Relief

Loratadine Oral Solution 5 mg/5 mL Antihistamine

Indoor & Outdoor Allergies

24 Hour Non-Drowsy† Allergy Relief of:
Runny Nose | Sneezing
Itchy, watery eyes
Itchy throat or nose

2 Yrs. & older
Sugar Free
Grape Flavor

Dosing Cup Included

4 FL OZ (120 mL)

QC QUALITY CHOICE NDC 63868-092-08

Compare to the active ingredient in Children's CLARITIN®

children's Allergy Relief

Loratadine Oral Solution 5 mg/5 mL Antihistamine

Indoor & Outdoor Allergies

• Alcohol Free
• Sugar Free
• 24 Hour Relief
• Dosage Cup Enclosed

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

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43157 W. Nine Mile
Novi, MI 48376-0995
www.qualitychoice.com
Questions: 248-449-9300

Made In Canada

NO COPY ON THIS FLAP FOR LOT # AND EXPIRY DATE PRINT

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QUALITY CHOICE CHILDRENS ALLERGY RELIEF

loratadine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-092
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
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:63868-092-08	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	02/27/2010	

Labeler - Chain Drug Marketing Association, Inc. (011920774)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(63868-092)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(63868-092)

Revised: 3/2014

Chain Drug Marketing Association, Inc.