

CARE ONE CHILDRENS LORATADINE- loratadine solution
American Sales Company

Care One®
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 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	ask a doctor

or kidney disease

ask a doctor

Other information

- do not use if carton is opened, or if imprinted safety seal is broken or missing
- see bottom panel for 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

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 41520-092-08

*Compare to the
Active Ingredient
in Children's
Claritin®**

CAREONE®

**24 HOUR/NON-DROWSY†
SUGAR FREE**

**CHILDREN'S
ALLERGY RELIEF**

*(Loratadine Oral Solution)
5 mg/5 mL Antihistamine*

Indoor & Outdoor Allergies
DYE FREE

**GRAPE FLAVORED
SYRUP** *Ages two years and older*

Relief of:
*Sneezing, Runny Nose,
Itchy, Watery Eyes,
Itchy Throat or Nose*

**Dosage Cup
Enclosed**

**4 FL OZ
[120 mL]**

† When taken as directed.
See Drug Facts Panel.

NO VARNISH
ON THIS FLAP

NDC 41520-092-08

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in Children's
Claritin®

CAREONE®

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Relief of:
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DISTRIBUTED BY
FOODHOLD U.S.A., LLC
LANDOVER, MD 20785
1-877-846-9949
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MADE IN CANADA

Quality guaranteed or your money back.

*This product is not manufactured or
distributed by MSD Consumer Care Inc.,
a subsidiary of Merck & Co., Inc.,
distributor of Children's Claritin®

† When taken as directed.
See Drug Facts Panel.

4 FL OZ
(120 mL)

NDC 41520-092-08

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ALLERGY RELIEF**

(Loratadine Oral Solution)
5 mg/5 mL Antihistamine

Indoor & Outdoor Allergies

DYE FREE



Dosage Cup
Enclosed

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SYRUP** Ages two years and older

Relief of:
Sneezing, Runny Nose,
Itchy, Watery Eyes,
Itchy Throat or Nose



† When taken as directed.
See Drug Facts Panel.

4 FL OZ
(120 mL)

NO VARNISH
ON THIS FLAP

PPK-7077-0
0813-0
M132

CAREONE®
24 HOUR/NON-DROWSY*
SUGAR FREE

**CHILDREN'S
ALLERGY RELIEF**

(Loratadine Oral Solution)
5 mg/5 mL Antihistamine

GRAPE FLAVORED SYRUP

NDC 41520-092-08

Compare to the
Active Ingredient
in Children's
Claritin®

CAREONE®

24 HOUR/NON-DROWSY*
SUGAR FREE

**CHILDREN'S
ALLERGY RELIEF**

(Loratadine Oral Solution)
5 mg/5 mL Antihistamine
Indoor & Outdoor Allergies

DYE FREE

GRAPE FLAVORED
SYRUP Ages two years and older



Relief of:
Sneezing, Runny Nose,

SEALED WITH PRINTED NECKBAND

Drug Facts

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

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CARE ONE CHILDRENS LORATADINE

loratadine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-092
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
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:41520-092-08	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 - American Sales Company (809183973)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(41520-092)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41520-092)