

**TOPCARE CHILDRENS LORATADINE- loratadine solution**  
**Topco Associates LLC**

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**TopCare®**  
**Children's Loratadine Syrup**

***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 **1-888-423-0139**

DISTRIBUTED BY  
TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007

**PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton**

**TopCare®**

NDC 36800-092-08

**ALCOHOL-FREE**

**Children's  
Loratadine  
Syrup**

(LORATADINE ORAL SOLUTION)  
5 mg/5 mL ANTIHISTAMINE

**24 hour Non-Drowsy†  
Allergy Relief Sugar Free**

**Indoor & Outdoor Allergies  
Ages two years and older**

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

**GRAPE  
FLAVOR**

**QUALITY  
GUARANTEED**

*COMPARE TO  
CHILDREN'S  
CLARITIN®  
active ingredients\**

4 FL OZ (120 mL)

†When taken as directed. See Drug Facts Panel.

**TopCare®**

ALCOHOL-FREE

# Children's Loratadine Syrup

(LORATADINE ORAL SOLUTION)  
5 mg/5 mL ANTIHISTAMINE

NDC 36800-092-08

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active ingredients\***

4 FL OZ (120 mL)

**TopCare®**

NDC 36800-092-08

ALCOHOL-FREE

# Children's Loratadine Syrup

(LORATADINE ORAL SOLUTION)  
5 mg/5 mL ANTIHISTAMINE

- Alcohol 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.

This TOP CARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

DISTRIBUTED BY  
TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007  
1-888-423-0139  
©TOPCO TAR213  
topcare@topco.com

When taken as directed. See Drug Facts Panel.

MADE IN CANADA

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

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**NO VARNISH  
ON THIS FLAP**

NDC 36800-092-08

ALCOHOL-FREE

**TopCare®**

# Children's Loratadine Syrup

(LORATADINE ORAL SOLUTION)  
5 mg/5 mL ANTIHISTAMINE

**24 hour Non-Drowsy†  
Allergy Relief Sugar Free  
Indoor & Outdoor Allergies  
Ages two years and older**

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



**GRAPE  
FLAVOR**

**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
- sneezing
- itchy, watery eyes
- 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.

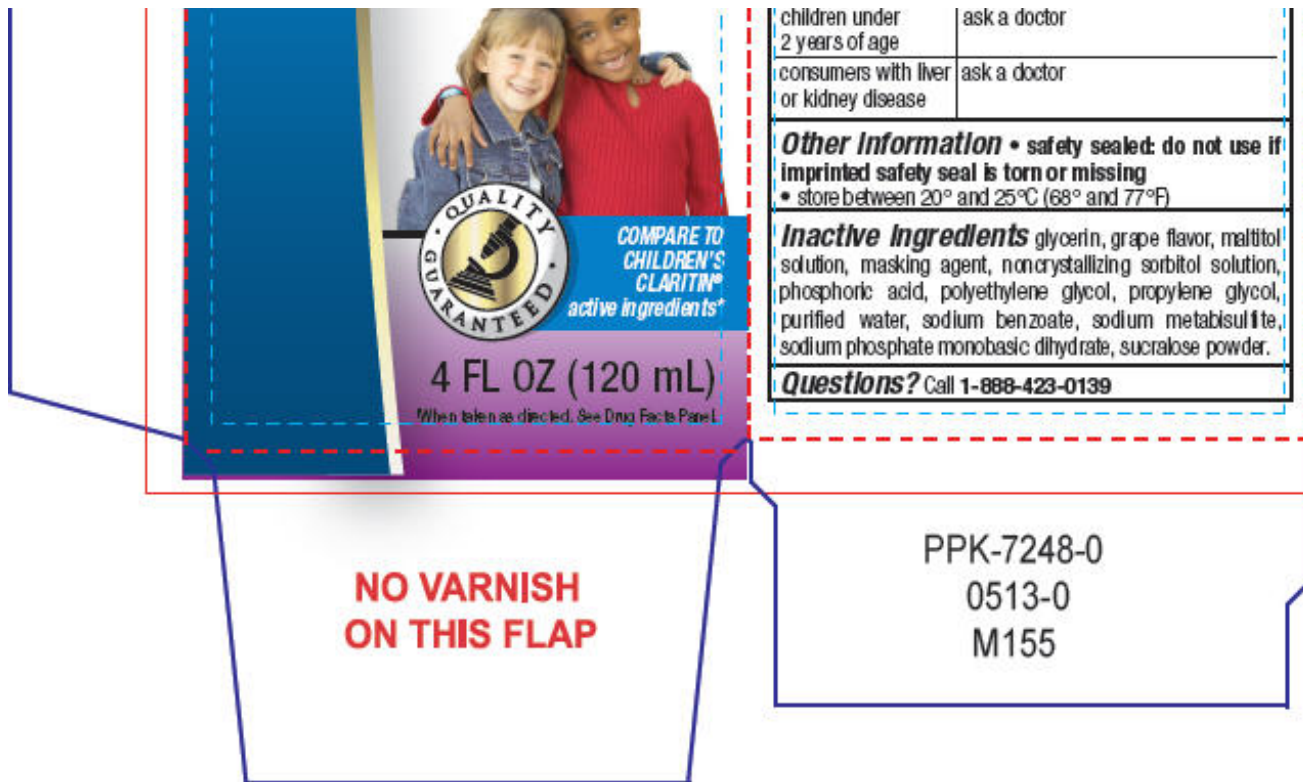
**Stop use and ask a doctor if** an allergic reaction to this product occurs. Seek medical help right away.

**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





## TOPCARE CHILDRENS LORATADINE

loratadine solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-092
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**

<b>Color</b>	YELLOW (colorless to slightly yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE (sugar free)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-092-08	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** - Topco Associates LLC (006935977)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(36800-092)

Revised: 6/2013

Topco Associates LLC