CHILDRENS NON-DROWSY ALLERGY RELIEF 24-HOUR- loratadine solution Kroger Company

Children's Non-Drowsy Allergy Relief 24-hour

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 or comments?

call 1-800-632-6900

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OH 45202

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

Compare to the active ingredient in CHILDREN'S CLARITIN[®] **See side panel.

NDC 30142-092-08

2 YEARS & Older

Non-drows y*

Children's

ALLERGY RELIEF

Loratadine Oral Solution 5 mg/5 mL

Antihis tamine

Dye-Free

24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

Sugar Free

Indoor & Outdoor Allergies

*When taken as directed. See Drug Facts Panel.

Grape Flavor

4 FL OZ (120 mL)

Kroger®

FROM OUR FAMILY TO YOURS



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 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. f pregnant or breast-feeding, ask a health professional hefore 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 2 teaspoonfuls (tsp) daily; do not take 6 years and over more than 2 teaspoonfuls (tsp) in 24 hours 1 teaspoonful (tsp) daily; do not take children 2 to under 6 years of age more than 1 teaspoonful (tsp) in 24 hours children under ask a doctor 2 years of age consumers with liver ask a doctor or kidney 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° Inactive ingredients glycerin, grape flavor, maltited 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 or comments? 1-800-632-6900 DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

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		WSY ALLERGY R	ELIEF 24-	HOUR			
oratadine solutio	DN						
Product Infor	mation						
Product T ype		HUMAN OTC DRUG	Item Code (S	ource)	NDC:	2:30142-092	
Route of Admini	stration	ORAL					
Active Ingred	ient/Active Moi	ety					
		edient Name		Basis of Stre	ngth	Strength	
Loratadine (UNII:	.oratadine (UNII: 7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN) Loratadine					5 mg in 5 mL	
Inactive Ingre	dients						
		Ingredient Name				Strength	
glycerin (UNII: PD							
sorbitol (UNII: 50)							
	(UNII: E4GA8884NN)						
	cols (UNII: 3WJQ0SD						
	(UNII: 6 DC9 Q 16 7 V3)					
water (UNII: 059Q							
	(UNII: OJ245FE5EU)						
	lfite (UNII: 4VON5FN						
sodium phosphat	e, monobasic, dihyo	lrate (UNII: 5QWK665956)					
Product Char	acteristics						
Color	YELLOW (colorle	ss to slightly yellow)		Score			
Shape				Size			
Flavor	GRAPE			Imp rint C	Code		
Contains							

Packaging								
# Item Code	Package Description	Marketing Start Date		Marketing End Date				
1 NDC:30142-092-08	1 in 1 CARTON							
1	120 mL in 1 BOTTLE							
Marketing Information								
Marketing Category	Application Number or Monograph Citation		Marketing Start D	ate Marketing End Date				
ANDA	ANDA076805		02/27/2010					

Labeler - Kroger Company (006999528)

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

Establishment							
Name	Address	ID/FEI	Business Operations				
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(30142-092)				

Revised: 8/2013

Kroger Company