ALLERGY RELIEF- loratadine solution Medicine Shoppe International Inc

Allergy Relief

Drug Facts

Active ingredient (in each 5 mL)

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.
- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.

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.

Directions

adults and children 6 years and over	2 teaspoonfuls daily; do not take more than 2 teaspoonfuls in 24 hours	
children 2 to under 6 years of age	1 teaspoonful daily; do not take more than 1 teaspoonful in 24 hours	
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 2° and 25°C (36° and 77°F)

Inactive ingredients

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

Distributed by:

Medicine Shoppe International, Inc.

St. Louis, Missouri 63132

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

The Medicine Shoppe[®]

†COMPARE TO ACTIVE INGREDIENT IN CHILDREN'S CLARITIN®

NDC 49614-174-26

NON-DROWSY*

Allergy

Relief

for

kids

Loratadine Oral Solution 5 mg/5 mL

Antihis tamine

RELIEF OF:

- □ SNEEZING
- □ **RUNNY NOSE**
- □ *I*TCHY, WATERY EYES
- □ *I*TCHY THROAT OR NOSE

FRUIT FLAVORED SYRUP

Ages two years and older

ALCOHOL FREE

DYE FREE

*When taken as directed. See Drug Facts Panel.

24

Hour



ALLERGY RELIEF

loratadine solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49614-174

Active Ingredient/Active Moiety

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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: C151H8M554)			

Product Characteristics			
Color	YELLOW (colorless to slightly yellow)	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49614-174-26	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 - Medicine Shoppe International Inc (071997654)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(49614-174)	