CHILDRENS LORATADINE- loratadine solution
Rite Aid Corporation

Children's Loratadine Syrup

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
- 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.
- 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 grape flavor, citric acid monohydrate, glycerin, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sucrose

DISTRIBUTED BY
RITE AID
CORPORATION
HARRISBURG,
PA 17105

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

RITE
AID
PHARMACY

Compare to active ingredient
in Children's Claritin®†

Original
Prescription
Strength

Children's

Loratadine
Syrup

(Loratadine
Oral Solution)
5 mg/5mL Antihistamine

Grape Flavored Syrup
Ages 2 years and older

24-Hour Allergy Relief
Non-Drowsy*

Relief of •Sneezing •Runny Nose

- Itchy, Watery Eyes
- Itchy Throat or Nose

4 FL OZ (120 mL)

***When Taken As Directed. See Drug Facts Panel**

SEALED WITH PRINTED NECKBAND

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Active ingredient (in each 5 mL) — **Purpose**

Loratadine 5 mg ..... Antihistamine

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- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

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RITE AID PHARMACY

Children's

Loratadine Syrup

RITE AID PHARMACY

Compare to active ingredient in Children's Claritin®†

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(Loratadine Oral Solution)
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0 11822 70929 3

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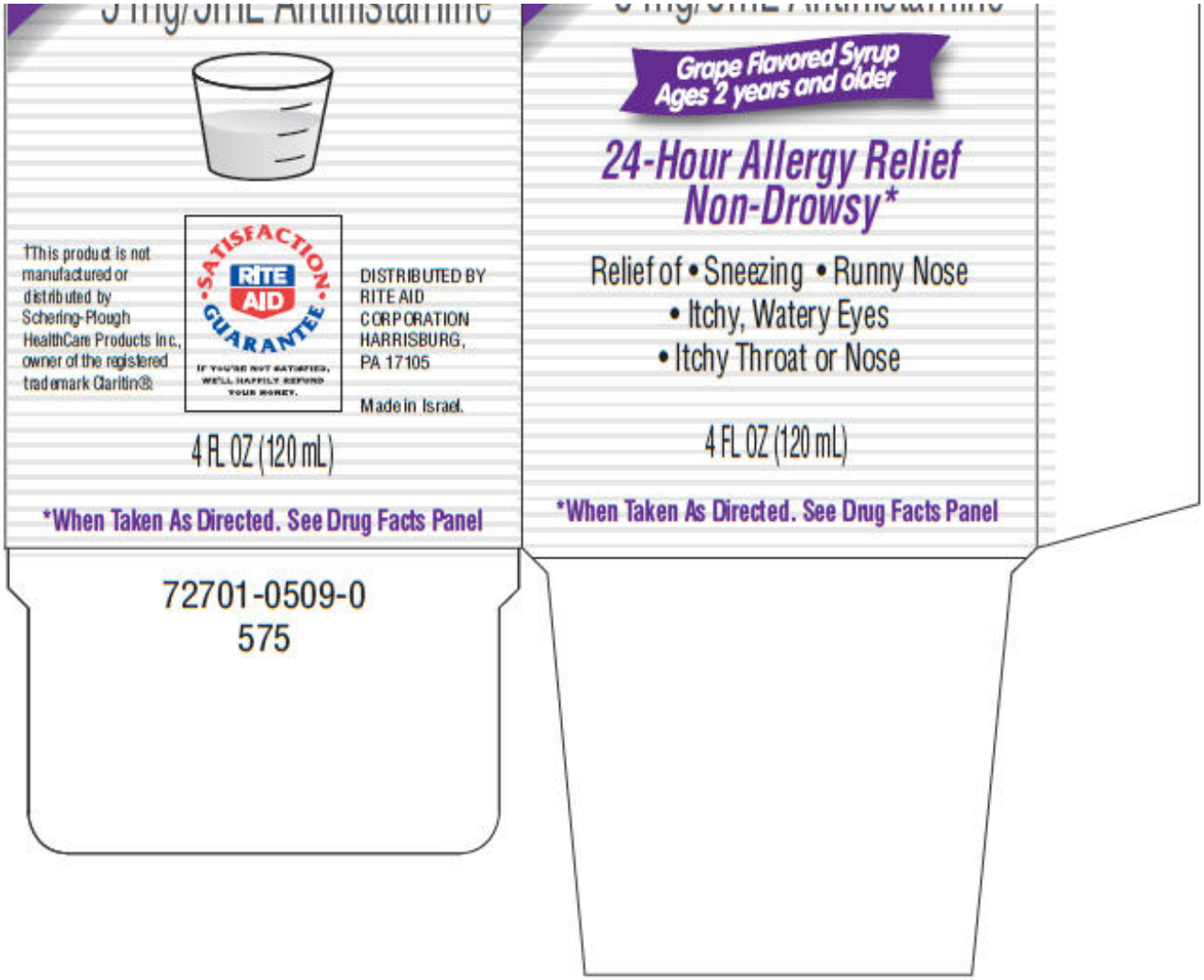

CHILDRENS LORATADINE

loratadine solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-0850
Route of Administration	ORAL	**DEA Schedule**	

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
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	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0850-8	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 - Rite Aid Corporation (014578892)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(11822-0850)

Revised: 11/2012 Rite Aid Corporation