

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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|---------------------------------------------|----------------|
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When taken AS Directed. See Drug Facts Panel



Compare to active ingredient
in Children's Claritin®†

Original
Prescription
Strength

Children's

**Loratadine
Syrup**



(Loratadine
Oral Solution)

5 mg/5ml Antihistamine

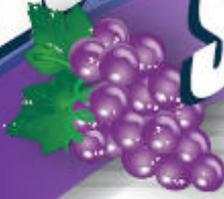


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CHILDRENS LORATADINE

loratadine solution

Product Information

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

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