SUNMARK CHILDRENS LORATADINE- loratadine solution McKesson

Sunmark[®] 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
- 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.

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

Questions?

Call 1-866-923-4914

Distributed by McKesson One Post Street, San Francisco, CA 94104

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

sunmark®

COMPARE TO CHILDREN'S CLARITIN[®] ACTIVE INGREDIENT*

NDC 49348 849-34

24 HOUR ALLERGY RELIEF

children's loratadine syrup

(Loratadine Oral Solution) 5 mg/5 mL Antihis tamine

Relief of sneezing, runny nose itchy, watery eyes itchy throat or nose

Dye Free Non-drowsy† Ages two years & older

GRAPE FLAVOR

4 FL OZ (120 mL)

† When taken as directed. See Drug Facts Panel.



SUNMARK CHILDRENS LORATADINE

loratadine solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49348-849

| Active Ingredient/ | Active Moiety | | | | | |
|---|--|---|---------------|-------------------------|--------------------|--|
| | | | Basis | is of Strength Strength | | |
| Loratadine (UNII: 7AJO | AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN) Lorata | | | dine 5 mg in 5 mL | | |
| | | | | | | |
| Inactive Ingredien | ts | | | | | |
| Ingredient Name | | | | | Strength | |
| citric acid monohydrat | itric acid monohydrate (UNII: 2968PHW8QP) | | | | U | |
| glycerin (UNII: PDC6A30 | | | | | | |
| propylene glycol (UNII: 6DC9Q167V3) | | | | | | |
| water (UNII: 059QF0KO | | | | | | |
| sodium benzoate (UNII: OJ245FE5EU) | | | | | | |
| sodium metabisulfite (UNII: 4VON5FNS3C) | | | | | | |
| sucrose (UNII: C151H8M5 | 554) | | | | | |
| | | | | | | |
| Product Character | ristics | | | | | |
| Color YEI | LLOW (colorless to slightly yellow) | | S | core | | |
| Shape | | | S | ize | | |
| Flavor GR. | GRAPE | | | Imprint Code | | |
| Contains | | | | | | |
| | | | | | | |
| Packaging | | | | | | |
| # Item Code | Package Description | Marketin | ng Start Date | Mar | rketing End Date | |
| 1 NDC:49348-849-34 | 1 in 1 CARTON | | | | | |
| 1 | 120 mL in 1 BOTTLE | | | | | |
| | | | | | | |
| | | | | | | |
| Marketing Information | | | | | | |
| Marketing Category | Application Number or Monogr | Application Number or Monograph Citation Marketin | | art Date | Marketing End Date | |
| ANDA | ANDA076805 | | 08/20/2004 | | | |
| | | | | | | |

Labeler - McKesson (177667227)

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------------|---------|-----------|----------------------------|
| Taro Pharmaceutical Industries Ltd. | | 600072078 | MANUFACTURE(49348-849) |