CHILDRENS LORATADINE- loratadine solution Kinray, Inc.

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 | 2 teaspoonfuls daily; do not take more than 2 |
|--|---|
| over | teaspoonfuls in 24 hours |
| children 2 to under 6 years of | 1 teaspoonful daily; do not take more than 1 |
| age | 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

Questions?

Call 1-866-923-4914

Distributed by: Kinray, Inc., Whitestone, NY 11357

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

Preferred

plus Pharmacy

Compare to the active ingredient in Claritin®*

Original

Prescription Strength

ages 2 yrs.& older

Children's

Loratadine

Syrup

(Loratadine

Oral Solution)

5 mg/5 mL

Antihistamine

Fruit Flavored Syrup 24 hour Non-Drowsy † **Allergy Relief**

Relief of:

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

SATISFACTION **GUARANTEED** Preferred

plus Pharmacy

4 FL OZ (120 mL)

[†] When taken as directed. See Drug Facts Panel.

Up to 24 days of relief

Children's Loratadine Svrup

(Lorataume Oral Solution) 5 mg/5 mL <u>Ant</u>ihistamine

Fruit flavored 24 hour Allergy Relief ages 2 yrs. & older



Compare to the active ingredient in Claritin®*

Original Prescription Strength

> ages 2 yrs. & older



Children's Loratadine Syrup



Fruit Flavored Syrup

24 hour Non-Drowsy * Allergy Relief

Relief of: Sneezing; Runny Nose, Itchy, Watery Eyes, Itchy Throat or Nose



Children's Loratadine Syrup

(Loratadine Oral Solution) 5 mg/5 mL Antihistamine

Fruit Flavored Syrup 24 hour Non-Drowsy * Allergy Relief

- 24 Hour Relief
- Alcohol-Free
- Fruit Flavored
- Dosage Cup Enclosed

*This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., owner of the registered trademark Claritin®.

All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from the retailer where purchased.

Distributed by: Kinray Inc. Whitestone NV 11357

4 FL OZ (120 mL)

[†] When taken as directed. See Drug Facts Panel.

Made in Israel.

REV. 4/10



SEALED WITH PRINTED NECKBAND

Drug Facts

Active ingredient (in each 5 mL)

Purpose Antibiotomino

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

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Your doctor should determine if you need a different dose.

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adults and children 6 years and over 2 teaspoonfuls daily; do not take more than 2 teaspoonfuls in 24 hours consumers with liver or kidney disease

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(Lorataaine Oral Solution) 5 mg/5 mL Antihistamine

Fruit Flavored Syrup

24 hour Non-Drowsy † Allergy Relief

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.

CHILDRENS LORATADINE

loratadine solution

| Product | Information |
|---------|-----------------|
| FIUUUCL | IIIIVI IIIauvii |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63777-073

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 | PEACH | Imprint Code | |
| Contains | | | |

| F | Packaging | | | |
|---|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:63777-073-08 | 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 - Kinray, Inc. (012574513)

| Establishment | | | | |
|--------------------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Taro Pharmaceutical Industries, Ltd. | | 600072078 | MANUFACTURE(63777-073) | |

Revised: 6/2012 Kinray, Inc.