

CHILDRENS LORATADINE SUGAR FREE- loratadine solution
CVS Pharmacy

Children's Loratadine Oral Solution
Sugar Free

Drug Facts

Active ingredient (in each 5 mL teaspoonful)

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. (1-800-222-1222)

Directions

- use only with enclosed dosing cup

| | |
|--------------------------------------|--|
| adults and children 6 years and over | 2 teaspoonfuls (tsp) daily; do not take more than 2 teaspoonfuls (tsp) in 24 hours |
| children 2 to under 6 years of age | 1 teaspoonful (tsp) daily; do not take more than 1 teaspoonful (tsp) in 24 hours |
| children under 2 years of age | ask a doctor |
| consumers with liver or | |

CONSUMERS WITH LIVER OR kidney disease | ask a doctor

Other information

- **do not use if bottle wrap imprinted with "SEALED FOR SAFETY" is broken or missing.**
- see bottom panel for lot number and expiration date
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

butylated hydroxyanisole, glycerin, grape flavor, maltitol solution, masking agent, phosphoric acid, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium phosphate monobasic dihydrate, sorbitol solution, sucralose powder.

Questions?

Call 1-866-923-4914

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 240 mL Bottle Carton

CVS

Health™

Compare to the active ingredient in Children's Claritin®†

Indoor & Outdoor

Allergies

NDC 69842-540-01

Children's

Allergy

LORATADINE

ORAL SOLUTION

USP, 5 mg/5 mL

(Antihistamine)

ALLERGY

Non-Drowsy*

24

HOUR

- **24 hour relief of:**
Sneezing; Runny nose; Itchy, watery eyes; Itchy throat or nose
- Sugar free & dye free
- **Ages 2 yrs & older**

*When taken as directed.

See Drug Facts Panel.

DYE

FREE

Grape Flavor

Dosing Cup Enclosed

Actual Product Size
on Back Panel

8 FL OZ (240 mL)



Indoor & Outdoor Allergies

Children's Allergy LORATADINE

NDC 69842-540-01

ORAL SOLUTION USP, 5 mg/5 mL (Antihistamine) ALLERGY



Compare to the active ingredient in Children's Claritin®†

Indoor & Outdoor Allergies

NDC 69842-540-01

Children's Allergy LORATADINE

ORAL SOLUTION USP, 5 mg/5 mL (Antihistamine) ALLERGY Non-Drowsy*



- 24 hour relief of: Sneezing; Runny nose; Itchy, watery eyes; Itchy throat or nose
- Sugar free & dye free
- Ages 2 yrs & older

*When taken as directed. See Drug Facts Panel.

DYE FREE



Grape Flavor Dosing Cup Enclosed



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8 FL OZ (240 mL)



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Indoor & Outdoor Allergies

NDC 69842-540-01

Children's Allergy LORATADINE

ORAL SOLUTION USP, 5 mg/5 mL (Antihistamine) ALLERGY Non-Drowsy*



- 24 hour relief of: Sneezing; Runny nose; Itchy, watery eyes; Itchy throat or nose
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- Ages 2 yrs & older

*When taken as directed. See Drug Facts Panel.

DYE FREE



Grape Flavor Dosing Cup Enclosed



Actual Product Size on Back Panel

8 FL OZ (240 mL)

NO COPY ON THIS FLAP FOR LOT # AND EXPIRY

T207

DATE PRINT

#912837



NO VARNISH ON THIS FLAP

SEALED WITH PRINTED NECKBAND

Dosing Cup Enclosed

Dosing cup should be washed and left to air dry after each use.



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Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
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CVS.com® 1-800-SHOP CVS

Made in Canada
V-16793



Package Contains One Bottle

Actual Size

Drug Facts

| Active ingredient (in each 5 mL teaspoonful) | Purpose |
|---|---------------|
| Loratadine 5 mg..... | Antihistamine |

Uses

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NO VARNISH
ON THIS FLAP

PPK-8639-0

1017-0

4

CHILDRENS LORATADINE SUGAR FREE

loratadine solution

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69842-540 |
| 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 |
|---|----------|
| butylated hydroxyanisole (UNII: REK4960K2U) | |
| glycerin (UNII: PDC6A3C0OX) | |
| SORBITOL (UNII: 506T60A25R) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| phosphoric acid (UNII: E4GA8884NN) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| water (UNII: 059QF0KO0R) | |
| sodium benzoate (UNII: OJ245FE5EU) | |
| SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956) | |

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:69842-540-01 | 1 in 1 CARTON | 11/10/2017 | |
| 1 | | 240 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:69842-540-08 | 1 in 1 CARTON | 11/10/2017 | |
| 2 | | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA076805 | 03/17/2017 | |

Labeler - CVS Pharmacy (062312574)

Revised: 11/2017

CVS Pharmacy