

CHILDRENS LORATADINE- loratadine tablet, chewable
CVS PHARMACY, INC

CHILDREN'S LORATADINE

Drug Facts

Active ingredient (in each tablet)

Loratadine USP, 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

| | |
|--|---|
| adults and children 6 years and over | chew 2 tablets daily; not more than 2 tablets in 24 hours |
| children 2 to under 6 years of age | chew 1 tablet daily; not more than 1 tablet in 24 hours |
| children under 2 years of age | ask a doctor |
| consumers with liver or kidney disease | ask a doctor |

Other information

- phenylketonurics: contains phenylalanine 1.25 mg per tablet.
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**
- store between 20° to 25°C (68° to 77°F).

Inactive ingredients

aspartame, citric acid anhydrous, colloidal silicon dioxide, D&C red No. 27 aluminum lake, FD&C blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions?

call **1-800-406-7984**

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 5 mg Tablet Blister Pack Carton

CVS
Health™

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

Indoor & Outdoor Allergies

NDC 69842-953-20

Children's
Allergy Relief
LORATADINE CHEWABLE
TABLETS USP, 5 mg
Antihistamine

24
HOUR

Non-Drowsy*

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

*When taken as directed.
See Drug Facts Panel.

Actual
Size

Grape
Flavor

20 CHEWABLE TABLETS

The chewable tablets are to be chewed before swallowing.

CVS Health.

Indoor & Outdoor Allergies

Children's

Allergy Relief

LORATADINE CHEWABLE TABLETS USP, 5 mg



Indoor & Outdoor Allergies



CVS Health.

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Indoor & Outdoor Allergies

NDC 69842-953-20

Children's

Allergy Relief

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Antihistamine

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#195770

R0119

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One CVS Drive, Woonsocket, RI 02895
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V-14192



CVS Health.

Children's

Allergy Relief

LORATADINE CHEWABLE TABLETS USP, 5 mg

Batch No.

Expiration Date:

Non Varnish Area



5195302

Drug Facts

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|---------------------------------------|---------------|
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Drug Facts (continued)

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Questions? call 1-800-406-7984

GLUE - NO COATING

†All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Children's Claritin® Chewables.

Keep the carton. It contains important information. See end panel for expiration date.

5195302



CHILDRENS LORATADINE

loratadine tablet, chewable

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69842-953

Route of Administration ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) | LORATADINE | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| aspartame (UNII: Z0H242BBR1) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| D&C RED NO. 27 (UNII: 2LRS185U6K) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| magnesium stearate (UNII: 70097M6I30) | |
| mannitol (UNII: 3OWL53L36A) | |
| microcrystalline cellulose (UNII: OP1R32D61U) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| stearic acid (UNII: 4ELV7Z65AP) | |

Product Characteristics

| | | | |
|----------|--------------------------------------|--------------|----------|
| Color | purple (light purple to dark purple) | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | GRAPE | Imprint Code | 753 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69842-953-20 | 2 in 1 CARTON | 05/01/2018 | |
| 1 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA210088 | 05/01/2018 | |

Labeler - CVS PHARMACY, INC (062312574)

Registrant - OHM LABORATORIES INC. (184769029)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

Revised: 2/2019

CVS PHARMACY, INC