

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
- 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.

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, carmine, citric acid anhydrous, colloidal silicon dioxide, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions?

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

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

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 69842-954-30

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
Bubblegum Flavor

30 CHEWABLE TABLETS

The chewable tablets are to be chewed before swallowing.

CVSHealth.

Indoor & Outdoor Allergies

Children's Allergy Relief

LORATADINE CHEWABLE TABLETS USP, 5 mg
Antihistamine



CVSHealth.

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

Indoor & Outdoor Allergies

NDC 69842-954-30

Children's Allergy Relief

LORATADINE CHEWABLE TABLETS USP, 5 mg
Antihistamine



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
Bubblegum Flavor



CVSHealth.

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

Non Varnish Area

Batch No.

Expiration Date:

30 CHEWABLE TABLETS

The chewable tablets are to be chewed before swallowing.

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
© 2018 CVS/pharmacy
CVS.com* 1-800-SHOP CVS

Made in India
V-14192



0718

#268797



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

Drug Facts

Active ingredient (in each tablet)	Purpose
Loratadine USP, 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

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).

Drug Facts (continued)

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).

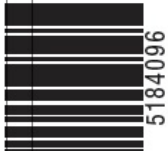
Inactive ingredients

aspartame, carmine, citric acid anhydrous, colloidal silicon dioxide, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

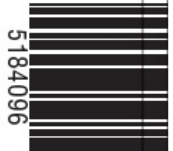
Questions? call 1-800-406-7984

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

GLUE - NO COATING



5184096



5184096

CHILDRENS LORATADINE

loratadine tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-954
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
aspartame (UNII: Z0H242BBR1)	
cochineal (UNII: TZ8Z31B35M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
magnesium stearate (UNII: 70097M6I30)	
mannitol (UNII: 3OWL53L36A)	
microcrystalline cellulose (UNII: OPIR32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
stearic acid (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	pink (light to medium pink with a slightly speckled appearance)	Score	no score
Shape	ROUND (Flat face, beveled edge)	Size	10mm
Flavor	BUBBLE GUM	Imprint Code	754
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-954-30	3 in 1 CARTON	07/01/2018	
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	07/01/2018	

Labeler - CVS PHARMACY, INC (062312574)

Registrant - Ohm Laboratories (051565745)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories		184769029	MANUFACTURE(69842-954)

Revised: 8/2018

CVS PHARMACY, INC