

**DYE-FREE CHILDRENS LORATADINE- loratadine tablet, chewable
CVS PHARMACY, INC**

Dye-Free Children's Loratadine

Drug Facts

Active ingredient (in each chewable 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

- chew or crush tablets completely before swallowing.

adults and children 6 years
and over

chew 2 tablets daily; not
more than 2 chewable

and over	tablets in 24 hours
children 2 to under 6 years of age	chew 1 tablet daily; not more than 1 chewable 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, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions?

call toll-free Monday to Friday 8:30 am to 5:00 pm EST at **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 51316-821-20

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+ years
- Dye free

*When taken as directed.
See Drug Facts Panel

Actual
Size

Grape
Flavor

20 CHEWABLE TABLETS

The chewable tablets are to be chewed before swallowing.

24
HOUR



DYE-FREE CHILDRENS LORATADINE			
loratadine tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-821

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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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	white (white to off-white)	Score	no score
Shape	ROUND (beveled edge)	Size	10mm
Flavor	GRAPE	Imprint Code	LC5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-821-20	2 in 1 CARTON	03/15/2024	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51316-821-30	3 in 1 CARTON	03/15/2024	
2		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	03/15/2024	

Labeler - CVS PHARMACY, INC (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(51316-821)

Revised: 3/2024

CVS PHARMACY, INC