

CHILDRENS LORATADINE- loratadine tablet, chewable
Amerisource Bergen

Children's Loratadine Chewable Tablets USP, 5 mg

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, 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 AmerisourceBergen
1300 Morris Drive, Chesterbrook, PA 19087

PRINCIPAL DISPLAY PANEL - 5 mg Tablet Blister Pack Carton

GOOD
NEIGHBOR
PHARMACY®

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

NDC 46122-550-60

ages 2 years and older

Non-Drowsy*
24 HOUR

Children's
loratadine chewable tablets USP, 5 mg
antihistamine

Indoor & Outdoor Allergies

Relief of:

- Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose

20 Chewable Tablets

The chewable tablets are to be chewed before swallowing.

*When taken as directed. See Drug Facts Panel.

actual size
grape flavor



Compare to Children's Claritin[®]
Chewables active ingredient**

Non-Drowsy*

Children's

loratadine chewable tablets USP, 5 mg
antihistamine



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1300 Morris Drive, Chesterbrook, PA 19087
Questions or Concerns?
Visit us at www.MyGNP.com

0718

ABC# 10188599



0 87701 43141 8

Non Varnish Area

Batch No.

Expiration Date:

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



Compare to Children's Claritin[®]
Chewables active ingredient**

Non-Drowsy*

Children's

loratadine chewable tablets USP, 5 mg
antihistamine

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

Drug Facts

Active ingredient (in each tablet) Loratadine USP, 5 mg; Antihistamine Purpose

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).

Other information ■ phenylethanolamine hydrochloride 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 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

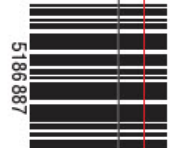
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Drug Facts (continued)



5186887



5186887

GLUE - NO COATING

CHILDRENS LORATADINE

loratadine tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-550
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: 70097M6B0)	
mannitol (UNII: 3OWL53L36A)	
microcrystalline cellulose (UNII: OP1R32D61U)	
stearic acid (UNII: 4ELV7Z65AP)	
sodium starch glycolate type a potato (UNII: 5856J3G2A2)	

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:46122-550-60	2 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 - Amerisource Bergen (007914906)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(46122-550)

Revised: 8/2018

Amerisource Bergen