

**CLARITIN CHEWABLE GRAPE AND BUBBLEGUM- loratadine**  
**Bayer HealthCare LLC.**

-----  
**Children's Claritin<sup>®</sup> Chewables 5mg Grape & Bubblegum UIs 1611948 & 1612741**

**Active ingredient (in each tablet)**

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.

**Directions**

- chew or crush tablets completely before swallowing.

---

adults and children 6 years and over	chew 2 tablets daily; not more than 2 chewable 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:

- grape flavor contains phenylalanine 1.4 mg per chewable tablet
- bubblegum flavor contains phenylalanine 1.9 mg per chewable tablet

safety sealed: do not use if the individual blister unit imprinted with Children's Claritin® is open or torn

store between 20° to 25°C (68° to 77°F)

## **Inactive ingredients**

### ***Grape chewable tablets***

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

### ***Bubblegum chewable tablets***

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

## **Questions or comments?**

**1-800-CLARITIN (1-800-252-7484)**

## **PRINCIPAL DISPLAY PANEL - 40 Chewable Tablet Blister Pack Carton**

VARIETY PACK

ages

2 +

years

Non-Drowsy\*

Children's

Claritin®

Chewables

loratadine chewable tablets

5 mg/antihistamine

24 Hour

Non-Drowsy\* Relief of:

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

Indoor & Outdoor Allergies

20 Grape Flavored

20 Bubblegum Flavored

\*When taken as directed. See Drug Facts Panel.

40 CHEWABLE TABLETS



## CLARITIN CHEWABLE GRAPE AND BUBBLEGUM

loratadine kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11523-0123
---------------------	----------------	---------------------------	----------------

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-0123-1	1 in 1 CARTON; Type 0: Not a Combination Product	09/01/2023	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		20
Part 2		20

### Part 1 of 2

#### CLARITIN

loratadine tablet, chewable

### Product Information

Item Code (Source)	NDC:11523-4330
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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
CARMINIC ACID (UNII: CID8Z8N95N)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

Color	pink (light to medium pink with a slightly and/or mottled appearance)	Score	no score
Shape	ROUND (round (flat faced beveled edge))	Size	10mm
Flavor	BUBBLE GUM	Imprint Code	C
Contains			

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021891	09/15/2015	

## Part 2 of 2

### CLARITIN

loratadine tablet, chewable

## Product Information

Item Code (Source)	NDC:11523-4331
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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

## Product Characteristics

Color	purple (Light to medium purple with a slightly speckled and/or mottled appearance)	Score	no score
Shape	ROUND (flat faced beveled edge)	Size	10mm
Flavor	GRAPE	Imprint Code	C
Contains			

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021891	08/23/2006	
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021891	08/23/2006	

**Labeler** - Bayer HealthCare LLC. (112117283)

Revised: 8/2023

Bayer HealthCare LLC.