

**CLARITIN- loratadine tablet, chewable**  
**Bayer HealthCare LLC.**

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**Claritin® Chewables**

**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
- 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.

**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 1.4 mg per 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**

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 or comments?**

**1-800-CLARITIN (1-800-252-7484) or [www.claritin.com](http://www.claritin.com)**

Dist by: Bayer HealthCare LLC, Whippany, NJ 07981

Product of Ireland

### **PRINCIPAL DISPLAY PANEL - 10 Chewable Tablet Blister Pack Carton**

NDC 11523-4328-1

*ages*

*2 years*

*and older*

*Children's*

*Claritin®*

*Allergy*

*loratadine 5 mg/antihistamine*

**Indoor & Outdoor**

**Allergies**

*Non-Drowsy\**

**24 Hour Relief of:**

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

**10 CHEWABLE TABLETS**

**Grape**

**Flavored**

**Chewables**

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

**Children's**  
**Claritin**<sup>®</sup>  
**Chewables** 



**10 CHEWABLE TABLETS**



**Children's**  
**Claritin**<sup>®</sup>  
**Chewables** 

*loratadine 5 mg/antihistamine*

**Indoor & Outdoor Allergies**

**Non-Drowsy\***  
**24 Hour Relief of:**

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



**10 CHEWABLE TABLETS**



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

**Drug Facts**

**Active ingredient (in each tablet)**      **Purpose**  
 Loratadine 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.

**Drug Facts (continued)**

<b>Directions</b> 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 1.4 mg per 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**

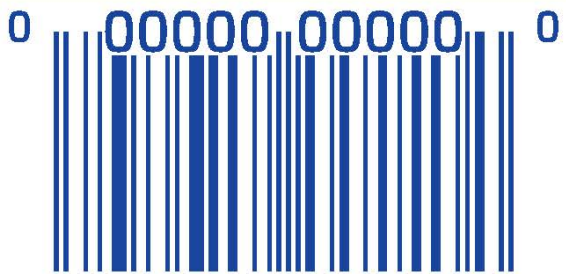
aspartame, citric acid anhydrous, colloidal silicon dioxide, D&C red No. 27 aluminum lake, FD&C blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

**Questions or comments?**

1-800-CLARITIN (1-800-252-7484) or [www.claritin.com](http://www.claritin.com)

Bayer

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 Whippany, NJ 07981  
 Product of Ireland.  
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**CLARITIN**

loratadine tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11523-4328
<b>Route of Administration</b>	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)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LM26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-4328-1	1 in 1 CARTON	08/23/2006	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11523-4328-2	2 in 1 CARTON	08/23/2006	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11523-4328-3	3 in 1 CARTON	08/23/2006	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:11523-4328-5	5 in 1 CARTON	08/23/2006	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:11523-4328-4	1 in 1 POUCH	08/23/2006	
5		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:11523-4328-7	2.5 in 1 PACKAGE, COMBINATION	08/23/2006	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:11523-4328-9	4 in 1 CARTON	08/23/2006	
7		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:11523-4328-6	50 in 1 BOX	08/23/2006	
8		2 in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

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

# CLARITIN

loratadine tablet, chewable

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11523-4331
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MANNITOL (UNII: 3OWL53L36A)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
ASPARTAME (UNII: Z0H242BBR1)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM OXIDE (UNII: LM26O6933)	

## Product Characteristics

<b>Color</b>	purple (Light to medium purple with a slightly speckled and/or mottled appearance)	<b>Score</b>	no score
<b>Shape</b>	ROUND (Flat Faced Beveled Edge)	<b>Size</b>	10mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	C
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-4331-1	4 in 1 CARTON	08/23/2006	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11523-4331-2	6 in 1 CARTON	09/06/2019	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11523-4331-3	2 in 1 CARTON	11/01/2019	
3		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

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

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

Revised: 10/2019

Bayer HealthCare LLC.