

CLARITIN CHEWABLE GRAPE AND BUBBLEGUM- loratadine
Bayer HealthCare LLC.

Children's Claritin[®] 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-0123
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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:11523-4331
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)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
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)	

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	

Part 2 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	
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: 12/2025

Bayer HealthCare LLC.