

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

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**Children Claritin® Chewables Perrigo**

**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**

artificial grape flavor, aspartame, colloidal silicon dioxide, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, 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

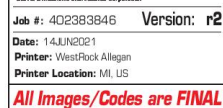
Product of Ireland

### **PRINCIPAL DISPLAY PANEL**

## 40 CT GRAPE CHEWABLE LORATADINE



the "d" in loratadine is Greater than 1/4 of the "C" in Claritin



**File Name:** C00011389\_CLARITIN\_Children\_Grape\_Tablet\_40Oct\_Carton\_r2

**NOTE: THIS COLOR PROOF INDICATES COLOR BREAK ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRODUCTION COLOR**

1	Cyan	5	PMS 287
2	Magenta	6	PMS 300
3	Yellow		Varnish
4	PMS 186		

**Method of Printing:**

- ☐ combo
- ☐ flexo
- ☒ offset
- ☐ screen
- ☐ gravure
- ☐ hot stamp
- ☐ digital

CATEGORY	REQUIRED
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Drug Facts title	>8 pt. <sup>1,2</sup>	9 pt.
Drug Facts Continued	6 pt.	6 pt.
Headings <sup>1</sup>	8 pt. bold italic <sup>3</sup>	8 pt.
Subheadings	<6 pt.	6 pt.
Body Text	<6 pt.	6 pt.
Bullets	5 pt.	3.5 pt.
Leading	>0.5 pt.	0.5 - 1 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines <sup>1</sup>	>0.5 pt. rule	1.5 pt.
Characters Per Inch	More than 30	<30

<sup>1</sup> Headings must be at least 2 pts larger than Body Text.

<sup>2</sup> Drug Facts titles be larger than all other type size used on ODP.

<sup>3</sup> FDA Recommends 2.5 pt. rule

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# CLARITIN

loratadine tablet, chewable

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-0104
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
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: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
ASPARTAME (UNII: Z0H242BBR1)	

## Product Characteristics

Color	purple (Light purple tablet with slightly mottled appearance)	Score	no score
Shape	ROUND	Size	10mm
Flavor	GRAPE	Imprint Code	C
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-0104-1	1 in 1 CARTON	02/08/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11523-0104-2	2 in 1 CARTON	02/08/2023	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11523-0104-3	3 in 1 CARTON	02/08/2023	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

4	NDC:11523-0104-4	4 in 1 CARTON	02/08/2023	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:11523-0104-5	6 in 1 CARTON	02/08/2023	
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:11523-0104-6	8 in 1 CARTON	02/05/2023	
6		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	ANDA210033	02/05/2023	

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

Revised: 6/2023

Bayer HealthCare LLC.