CLARITIN- loratadine tablet, chewable
Bayer HealthCare LLC.

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**

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.***

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
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

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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.

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Drug Facts (continued)

Directions

adults and children 6 years and over	chew 2 tablets daily; not more than 2 tablets in 24 hours
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Questions or comments?

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Children's Claritin® Chewables

Dist by: Bayer HealthCare LLC
Whippany, NJ 07981
Product of Ireland.
XXXXX-XX

Bayer

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CLARITIN

loratadine tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11523-4328
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
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 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			

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

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11523-4331
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MANNITOL (UNII: 3OWL53L36A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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: LMI26O6933)	

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

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:11523-4331-6	8 in 1 CARTON	08/23/2006	
3		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
NDA	NDA021891	08/23/2006	

Labeler - Bayer HealthCare LLC. (112117283)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Manufacturing Services LLC		079415560	manufacture(11523-4328)

Revised: 6/2023 Bayer HealthCare LLC.