

**LORATADINE- loratadine tablet
Bryant Ranch Prepack**

Loratadine Tablets, 10 mg

ACTIVE INGREDIENT(S)

Loratadine 10 mg

PURPOSE

Antihistamine

USE(S)

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, water 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 DOCTOR IF

an allergic reaction to this product occurs. Seek medical help right away.

PREGNANCY/BREASTFEEDING

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	1 tablet daily; not more than 1 tablet in 24 hours
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

OTHER INFORMATION

Tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken

Blister Foil Units

safety sealed: do not use if the individual blister unit is open or torn

STORAGE

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

INACTIVE INGREDIENTS

Lactose monohydrate, magnesium stearate, sodium starch glycolate and starch maize pregelatinized

QUESTIONS OR COMMENTS

Contact 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST.

HOW SUPPLIED

Loratadine 10 mg: white (white to off white), round shaped and the imprint code is G;10.

NDC: 71335-2529-1: 20 Tablets in a BOTTLE

NDC: 71335-2529-2: 30 Tablets in a BOTTLE


NDC: 71335-2529-3: 60 Tablets in a BOTTLE

NDC: 71335-2529-4: 14 Tablets in a BOTTLE

NDC: 71335-2529-5: 10 Tablets in a BOTTLE
 NDC: 71335-2529-6: 90 Tablets in a BOTTLE
 NDC: 71335-2529-7: 28 Tablets in a BOTTLE
 NDC: 71335-2529-8: 15 Tablets in a BOTTLE
 NDC: 71335-2529-9: 100 Tablets in a BOTTLE
 store between 20° to 25°C (68° to 77°F)

Repackaged/Relabeled by:
 Bryant Ranch Prepack, Inc.
 Burbank, CA 91504

Loratadine 10mg Tablet


 Lot 208820 Exp 11/25/2026 SN 0123456789 GTIN 0037135252915	Drug Facts	
	Active ingredient (in each tablet) Loratadine 10 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 (1-800-222-1222) right away.	
	Other information •store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature) •protect from light	
	Directions •adults and children 6 years and over: 1 tablet daily; not more than 1 tablet in 24 hours. •children under 6 years of age: ask a doctor. •consumers with liver or kidney disease: ask a doctor.	
Inactive Ingredients lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.		

NDC 71335-2529-1

Loratadine Tablets, USP

10 mg

20 Tablets



Repackaged by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Granules India Ltd.



Package Insert

LORATADINE			
loratadine tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71335-2529(NDC:70010-162)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)	LORATADINE	10 mg
Inactive Ingredients			
	Ingredient Name		Strength
	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
	STARCH, CORN (UNII: O8232NY3SJ)		
	MAGNESIUM STEARATE (UNII: 70097M6I30)		
	SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		

Product Characteristics

Color	white (White to off white)	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	G;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-2529-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2024	
2	NDC:71335-2529-2	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2024	
3	NDC:71335-2529-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2024	
4	NDC:71335-2529-4	14 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2024	
5	NDC:71335-2529-5	10 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2024	
6	NDC:71335-2529-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2024	
7	NDC:71335-2529-7	28 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2024	
8	NDC:71335-2529-8	15 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2024	
9	NDC:71335-2529-9	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210722	01/01/2020	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-2529) , RELABEL(71335-2529)

Revised: 11/2024

Bryant Ranch Prepack