# LORATADINE - loratadine tablet Bryant Ranch Prepack

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# Loratadine tablets USP, 10mg/antihistamine

# **ACTIVE INGREDIENT(S)**

Active ingredient (in each tablet)

Loratadine USP, 10 mg

#### **PURPOSE**

**Antihistamine** 

## USE(S)

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

<ul><li>runny nose</li></ul>	■ itchy, watery eyes
<ul><li>sneezing</li></ul>	<ul><li>itching of the nose or throat</li></ul>

### 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.

### ASK A DOCTOR OR PHARMACIST BEFORE USE IF

# 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

#### **Bottles:**

- Tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken
- store between 20° to 25°C (68° to 77°F)

### Blisters packs:

- safety sealed: do not use if the individual blister unit imprinted with loratadine is open or torn
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

### **INACTIVE INGREDIENTS**

corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

# **QUESTIONS OR COMMENTS?**

Call 1-888-588-1418

### **HOW SUPPLIED**

Loratadine USP, 10 mg: color white (White to Off white) and the imprint code is H;L20.

NDC: 71335-2551-1: 20 Tablets in a BOTTLE

NDC: 71335-2551-2: 30 Tablets in a BOTTLE

NDC: 71335-2551-3: 60 Tablets in a BOTTLE

NDC: 71335-2551-4: 14 Tablets in a BOTTLE

NDC: 71335-2551-5: 10 Tablets in a BOTTLE

NDC: 71335-2551-6: 90 Tablets in a BOTTLE

NDC: 71335-2551-7: 28 Tablets in a BOTTLE

NDC: 71335-2551-8: 15 Tablets in a BOTTLE

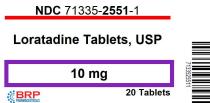
NDC: 71335-2551-9: 100 Tablets in a BOTTLE

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

# Loratadine 10mg Tablet











# **LORATADINE**

loratadine tablet

#### **Product Information**

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:71335-2551(NDC:69230-323)

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) LORATADINE 10 mg

# **Inactive Ingredients**

Ingredient Name Strength
STARCH, CORN (UNII: 08232NY3SJ)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

MAGNESIUM STEARATE (UNII: 70097M6I30)

## **Product Characteristics**

 Color
 white (White to Off white)
 Score
 no score

 Shape
 ROUND
 Size
 6mm

 Flavor
 Imprint Code
 H;L20

 Contains

Pac	

gg				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335- 2551-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2025	
2	NDC:71335- 2551-2	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2025	
3	NDC:71335- 2551-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2025	

4	NDC:71335- 2551-4	14 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2025	
5	NDC:71335- 2551-5	10 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2025	
6	NDC:71335- 2551-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2025	
7	NDC:71335- 2551-7	28 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2025	
8	NDC:71335- 2551-8	15 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2025	
9	NDC:71335- 2551-9	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2025	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA211718	07/28/2023	

# Labeler - Bryant Ranch Prepack (171714327)

# Registrant - Bryant Ranch Prepack (171714327)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bryant Ranch Prepack		171714327	REPACK(71335-2551), RELABEL(71335-2551)	

Revised: 1/2025 Bryant Ranch Prepack