## LORATADINE - loratadine tablet Camber Consumer Care Inc

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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
- 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. (1-800-222-1222)

#### **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

#### **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 1-888-588-1418 Mon-Fri 8:00 AM EST to 5:00 PM EST

#### PRINCIPAL DISPLAY PANEL

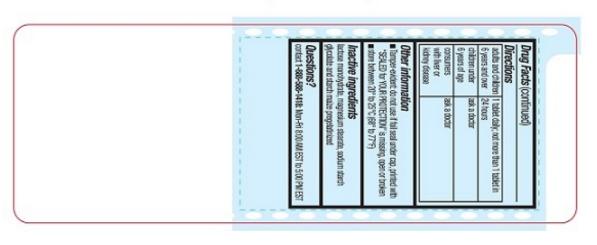
Loratadine 10 mg 100-count Carton Label



Loratadine 10 mg 100-count Container Label



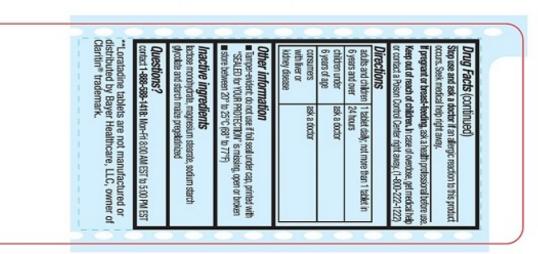
Inside (adhesive side)



Loratadine 10 mg 300-count Container Label



# Inside (adhesive side)



## LORATADINE

loratadine tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69230-328	
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		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
STARCH, CORN (UNII: O8232NY3SJ)		

MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856 3G2A2)	

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69230-328- 01	1 in 1 CARTON	07/31/2022		
1		100 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:69230-328- 03	300 in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2022		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210722	07/31/2022	

# Labeler - Camber Consumer Care Inc (079539968)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Granules India Limited		918609236	manufacture(69230-328)	

Revised: 12/2022 Camber Consumer Care Inc