# LORATADINE - loratadine tablet Camber Consumer Care Inc

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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**

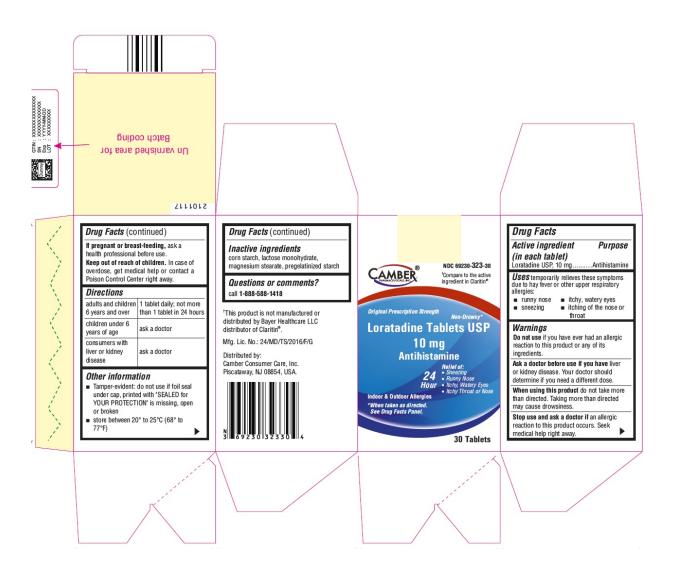
corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

## **QUESTIONS OR COMMENTS?**

Call 1-888-588-1418

### PRINCIPAL DISPLAY PANEL

Loratadine-tablets-USP-10mg-30's-carton



#### Loratadine-tablets-USP-10mg-30's-container



Loratadine-tablets-USP-10mg-100's-carton



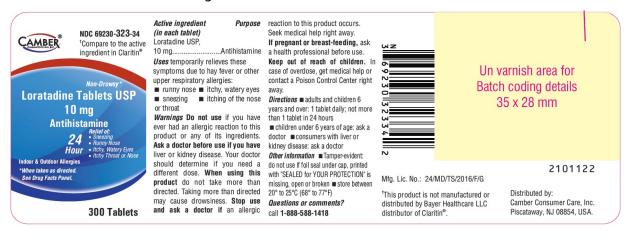
# Loratadine-tablets-USP-10mg-100's-container



Loratadine-tablets-USP-10mg-300's-carton



# Loratadine-tablets-USP-10mg-300's-container



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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: O8232NY3SJ)			
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				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69230- 323-30	1 in 1 CARTON	07/28/2023			
1		30 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:69230- 323-31	1 in 1 CARTON	07/28/2023			
2		108 in 1 BOTTLE; Type 0: Not a Combination Product				
3	NDC:69230- 323-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2023			
4	NDC:69230- 323-01	10 in 1 CARTON	07/28/2023			
4	NDC:69230- 323-32	10 in 1 BLISTER PACK; Type 0: Not a Combination Product				
5	NDC:69230- 323-33 1 in 1 CARTON		07/28/2023			
5		100 in 1 BOTTLE; Type 0: Not a Combination Product				
6	NDC:69230- 323-34	1 in 1 CARTON	07/28/2023			
6		300 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information						
Marketing Category						
ANDA	ANDA211718	07/28/2023				

# **Labeler -** Camber Consumer Care Inc (079539968)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Annora Pharma Private Limited		650980746	manufacture(69230-323)	

Revised: 9/2023 Camber Consumer Care Inc