

**LORATADINE- loratadine tablet**  
**NuCare Pharmaceuticals, Inc.**

-----  
**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.

## **PRINCIPAL DISPLAY PANEL**

NDC: 68071-3596-9

**Loratadine 10mg  
#90 Tablets**

Each tablet contains: Loratadine USP 10mg..... Antihistamine  
**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. In case of overdose, get medical help or contact a Poison Control Center right away. Round white tablet imprint "G" on one side "10" on the other side

Product #: P0653090

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

Loratadine 10mg  
 Lot: 00000 NDC: 68071-3596-09  
 MFR NDC: 70010-162-34 Exp.: 00-00  
 Serial# 0000000002

Loratadine 10mg  
 Lot: 00000 NDC: 68071-3596-09  
 MFR NDC: 70010-162-34 Exp.: 00-00  
 Serial# 0000000002

GTIN 00368071359695  
 Serial# 0000000002  
 Exp. Date 00-00  
 LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Distributed by: 3 6807135969 5  
 Granules Pharmaceuticals Inc.  
 Chantilly, VA 20151  
 Packaged By:  
 NuCare Pharmaceuticals, Inc.  
 Orange, CA 92667  
**Patent Instructions:**  
 Take \_\_\_\_\_ every \_\_\_\_\_ hours  
 \_\_\_\_\_ times a day.  
 6807135969-90-00000-00000

Rev 01/01/19

**LORATADINE**

loratadine tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68071-3596(NDC:70010-162)
<b>Route of Administration</b>	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
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start	Marketing End
---	-----------	---------------------	-----------------	---------------

#	Item Code	Package Description	Date	Date
1	NDC:68071-3596-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2024	
2	NDC:68071-3596-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2024	

## Marketing Information

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

**Labeler** - NuCare Pharmaceuticals, Inc. (010632300)

## Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-3596)

Revised: 8/2024

NuCare Pharmaceuticals, Inc.