

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

NuCare Pharmaceuticals, Inc.

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
 Patient Instructions
 Take every hours
 times a day.
 6807135969-90-00000-00000
 Rev 01/01/19

LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-3596(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: O8232NY3S)	
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	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:68071-3596-9	90 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: 4/2024

NuCare Pharmaceuticals, Inc.