

LORATADINE- loratadine tablet
NuCare Pharmaceuticals, Inc.

788S (658)

Active ingredient (in each tablet)

Loratadine, USP 10 mg

Purpose

Antihistamine

Uses

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

- runny nose
- sneezing
- itching of the nose and throat
- itchy, watery eyes

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.

Directions

adults and children 12 years and over	1 tablet daily; not more than 1 tablet in 24 hours
children under 12	

children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.
- store between 20° to 25°C (68° to 77°F)
- protect from light

Inactive ingredients

lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions?

call **1-800-540-3765**

package label

NuCare Pharmaceuticals, Inc.

NDC: 68071-2392-3
Loratadine 10mg #30 Tablets
 See manufacturer's label for full list of ingredients.

Loratadine 10mg
 Lot: 00000 NDC: 68071-2392-03
 MFR NDC: 57896-658-03 Exp.: 00-00
 Serial# 0000000002

Loratadine 10mg
 Lot: 00000 NDC: 68071-2392-03
 MFR NDC: 57896-658-03 Exp.: 00-00
 Serial# 0000000002

GTIN 00368071239232
 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.

Product #: R0824030
 STORE AT CONTROLLED TEMPERATURE 68-77°F.

WARNING: KEEP OUT OF REACH OF CHILDREN

LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-2392(NDC:57896-658)
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
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	439
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2392-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075209	02/01/2020	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-2392)

Revised: 4/2021

NuCare Pharmaceuticals,Inc.