LORATADINE - loratadine tablet
Aurohealth LLC

Loratadine Tablets USP 10 mg

Drug Facts

Active ingredient (in each tablet)

Loratadine USP 10 mg

Purpose

Antihistamine

Uses

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 (1-800-222-1222) 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
- store at 20° to 25°C (68° to 77°F)
- protect from excessive moisture

Inactive ingredients

lactose monohydrate, magnesium stearate, pregelatinized starch (maize), sodium starch glycolate.

Questions or comments?

call **1-855-274-4122**

Distributed by: **AUROHEALTH LLC**
2572 Brunswick Pike
Lawrenceville, NJ 08648
Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (90 Tablets Bottle)

HealthyLiving

NDC 58602-847-19

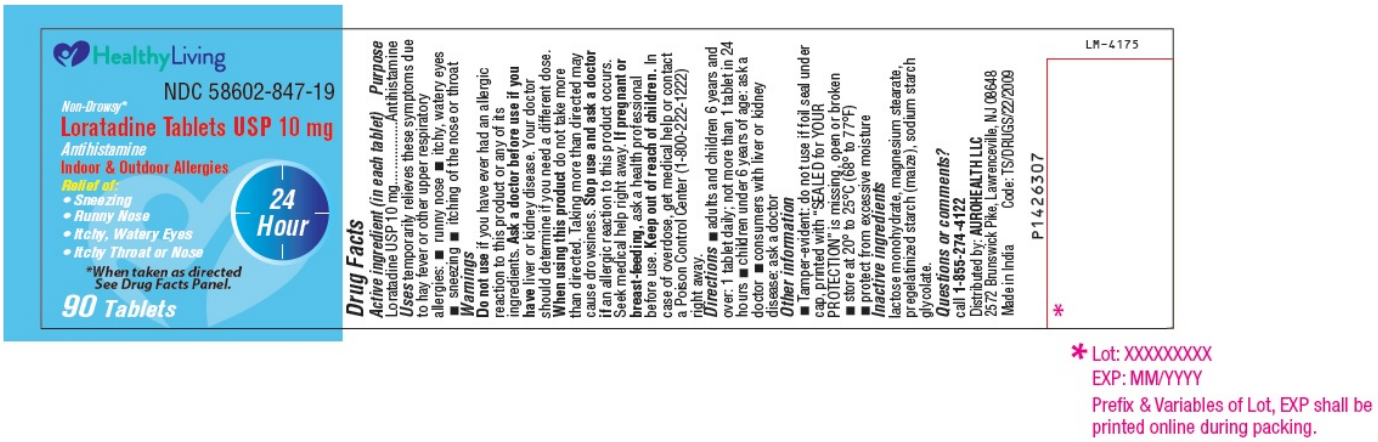
*Non-Drowsy**
Loratadine Tablets USP 10 mg
Antihistamine
Indoor & Outdoor Allergies
Relief of:

- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**
- ***Itchy Throat or Nose***

24 Hour

***When taken as directed See Drug Facts Panel**

90 Tablets



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg Container Carton (90 Tablets)

HealthyLiving

NDC 58602-847-19
#Compare to the active

Ingredient in Claritin®

*Non-Drowsy**
Loratadine

Tablets USP 10 mg *Antihistamine* Indoor & Outdoor Allergies
Relief of:

- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**
- ***Itchy Throat or Nose***

24 Hour

***When taken as directed See Drug Facts Panel.**

90 Tablets

LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-847
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
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**	39;L
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-847-19	1 in 1 CARTON	05/16/2020	
1		90 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208314	05/16/2020	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-847) , MANUFACTURE(58602-847)

Revised: 5/2020 Aurohealth LLC