

**LORATADINE - loratadine tablet**  
**Aurohealth LLC**

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**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 (45 Tablets Bottle)**

**NDC 58602-831-17**

**PH primary Health**

**Non-Drowsy\***

**Allergy Relief**

**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.**

**45 Tablets**

NDC 58602-831-17		LM-3197
		
<b>Non-Drowsy*</b> <b>Allergy Relief</b> Loratadine Tablets USP 10 mg		
Antihistamine Indoor & Outdoor Allergies		
<b>Relief of:</b> • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose		
	<b>45 Tablets</b>	
<small>*When taken as directed See Drug Facts Panel.</small>		
<b>Drug Facts</b> <b>Active ingredient (in each tablet):</b> Purpose Loratadine USP 10 mg. 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 <b>Warnings</b> Do not use if you have ever had an allergic reaction to this product or any of its ingredients. <b>Ask a doctor before use if you have liver or kidney disease.</b> Your doctor should determine if you need a different dose. <b>When using this product</b> do not take more than directed. Taking more than directed may cause drowsiness. <b>Stop use and ask a doctor if an allergic reaction to this product occurs.</b> Seek medical help right away. <b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. <b>Directions</b> ■ 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 <b>Other information</b> ■ 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 <b>Inactive ingredients</b> lactose monohydrate, magnesium stearate, pregelatinized starch (maize), sodium starch glycolate. <b>Questions or comments?</b> call 1-855-274-4122 Distributed by: <b>AUROHEALTH LLC</b> 2572 Brunswick Pike, Lawrenceville, NJ 08648 Made in India Code: TS/DRUGS/22/2009		

\* Lot: XXXXXXXX  
EXP: MM/YYYY  
Prefix & Variables of Lot, EXP shall be printed online during packing.

## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg Container Carton (45 Tablets)

**NDC 58602-831-17**  
**PH primary Health**  
**Non-Drowsy\***  
**Allergy Relief**  
**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.**

**45 Tablets**



**LORATADINE**

loratadine tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-831
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LORATADINE</b> (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	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:58602-831-17	1 in 1 CARTON	04/16/2018	
1		45 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-831-19	1 in 1 CARTON	04/16/2018	
2		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	04/16/2018	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-831) , MANUFACTURE(58602-831)

Revised: 11/2022

Aurohealth LLC