

**LORATADINE- loratadine tablet**  
**American Health Packaging**

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**Loratadine Tablets, USP Antihistamine**  
**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:

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

***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 (1-800-222-1222).

## **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**

- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture
- **FOR YOUR PROTECTION:** Do not use if blister is torn or broken.

## **Inactive Ingredients**

Corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

## **Questions?**

for Ohm Laboratories call 1-800-406-7984

The drug product contained in this package is from NDC # 51660-526, Ohm Laboratories Inc.

Packaged and Distributed by:  
American Health Packaging, Columbus, Ohio 43217

**Principal Display Panel - Carton - 10 mg**

NDC 68084-248-01

**Loratadine Tablets, USP**

**10 mg**

100 Tablets (10 x 10)



**Drug Facts**

<b>Active ingredient (in each tablet)</b> Loratadine, USP 10 mg	<b>Purpose</b> Antihistamine
<b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ itching of the nose or throat ■ runny nose     ■ itchy, watery eyes     ■ sneezing	
<b>Warnings</b> <b>Do not use</b> 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</b> liver or kidney disease. 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.	

NDC 68084-248-01

NON-DROWSY\* 24 Hour Allergy Relief

**Loratadine Tablets, USP**

**Antihistamine** Indoor & Outdoor Allergies

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

**10 mg**

100 Tablets (10 x 10)

**Drug Facts (continued)**

<b>Stop use and ask a doctor if</b> an allergic reaction to this product occurs. 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 right away (1-800-222-1222).	
<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> ■ store between 20° to 25°C (68° to 77°F) ■ protect from excessive moisture     ■ <b>FOR YOUR PROTECTION:</b> Do not use if blister is torn or broken.	
<b>Inactive Ingredients</b> corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch.	
<b>Questions?</b> for Ohm Laboratories call 1-800-406-7984	

The drug product contained in this package is from  
NDC # 51660-526, Ohm Laboratories Inc.  
Packaged and Distributed by: 801697  
American Health Packaging, Columbus, Ohio 43217 0224801/0119

NDC 68084- 248-01

NON-DROWSY\* 24 Hour Allergy Relief

**Loratadine** Tablets, USP

**Antihistamine** Indoor & Outdoor Allergies

**10 mg**

**100 Tablets (10 x 10)**

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

The drug product contained in this package is from  
NDC # 51660-526, Ohm Laboratories Inc.

Packaged and Distributed by:

American Health Packaging, Columbus, Ohio 43217

801697

0224801/0119

## Principal Display Panel - Blister - 10 mg

Allergy Relief  
Loratadine  
Tablet, USP 10 mg  
  
(01) 003 68084 248 11 5  
American Health Packaging, Columbus, Ohio 43217

Expiry: xx/xx  
Lot: xxxxxx

Expiry: xx/xx  
Lot: xxxxxx

Allergy Relief  
Loratadine  
Tablet, USP 10 mg  
  
(01) 003 68084 248 11 5  
American Health Packaging, Columbus, Ohio 43217

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Allergy Relief  
Loratadine  
Tablet, USP 10 mg  
  
(01) 003 68084 248 11 5  
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Allergy Relief  
Loratadine  
Tablet, USP **10 mg**

## LORATADINE

loratadine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68084-248(NDC:51660-526)
<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
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

## 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>	RX526
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68084-248-01	100 in 1 BOX, UNIT-DOSE	11/09/2007	
1	NDC:68084-248-11	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		



### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076134	11/09/2007	

**Labeler** - American Health Packaging (929561009)

### Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(68084-248)

Revised: 10/2022

American Health Packaging