

## **LORATADINE- loratadine tablet**

### **Major Pharmaceuticals**

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### **Major Pharmaceuticals Allergy Drug Facts**

#### **Active ingredient (in each tablet)**

Loratadine 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 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

- do not use if printed foil under cap is broken or missing
- store between 20° to 25°C (68° to 77°F)

## Inactive ingredients

lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

## Questions or comments?

**1-800-719-9260**

## Other Safety Information

**This Unit Dose package is not child resistant and is intended for Institutional Use Only.**

## Gluten Free

The drug product contained in this package is from NDC # 0904-6852, Major® Pharmaceuticals

Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268 USA

[www.major-rugby.com](http://www.major-rugby.com)

LBLN0296-01

Rev. 03/25	M-05	Re-order No. 303078
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## Principal Display Panel

MAJOR®

NDC 0904-7511-61

Unit Dose

Original Prescription Strength

**Loratadine**

**Tablets**

**10 mg**

Antihistamine

100 TABLETS (10 x 10)

**MAJOR®**

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(01)00309047511617

**LORATADINE**

loratadine tablet

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7511(NDC:0904-6852)	
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

  

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	L612
Contains			

  

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7511-61	100 in 1 CARTON	03/18/2025	
1		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	ANDA076301	03/18/2025	

**Labeler -**
Major Pharmaceuticals (191427277)