LORATADINE- loratadine tablet
Cardinal Health 107, LLC

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

Overbagged with 10 tablets per bag, NDC 55154-0188-0

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

Distributed By:

Cardinal Health

Dublin, OH 43017

L60439210825

LBLN0296-01

Rev. 03/25	M-05	Re-order No. 303078

Principal Display Panel

NDC 55154-0188-0

Original Prescription Strength

LORATADINE TABLETS, 10 mg

Antihistamine

10 TABLETS

B114

NDC 55154-0188-0

Original Prescription Strength
LORATADINE TABLETS, 10 mg
Antihistamine

10 TABLETS

Drug Facts
Active ingredient (in each tablet)
Loratadine 10 mg **Purpose: Antihistamine**

Inactive Ingredients: lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

Uses: temporarily relieves these symptoms due to hay fever or other respiratory allergies:
■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose or throat

Directions:

adults and children 6 years and over	**take 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.**

STORAGE: Store between 20° to 25°C (68° to 77°F)

WARNING: 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 and ask a doctor if an allergic reaction occurs. Seek medical help right away.
If pregnant or breast feeding, ask a health professional before use.
Keep out of reach of children. This Unit Dose package is not child resistant and is Intended for Institutional Use Only.
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Lot: **Exp:**

LORATADINE
loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55154-0188(NDC:0904-7511)
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)	
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:55154-0188-0	10 in 1 BAG	08/28/2025	
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	08/28/2025	

Labeler - Cardinal Health 107, LLC (118546603)

Revised: 8/2025 Cardinal Health 107, LLC