

LORATADINE- loratadine tablet

Major Pharmaceuticals

Loratadine 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

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**This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Claritin® Tablets.

Cartons of 100 tablets (10 tablets each blister pack x 10), NDC 0904-7511-61

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep this and all drugs out of the reach of children.

Distributed by MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

www.major-rugby.com

Packaged and Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268 USA

Refer to package label for Distributor's NDC Number

Rev. 04/25	M-05	Re-order No. 701027
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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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MAJOR®

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Questions or comments? 1-800-719-9260

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
LBLN0296-01

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



(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)