

LORATADINE- loratadine tablet
Mylan Institutional Inc.

Drug Facts

*Original Prescription Strength Non-Drowsy**

Indoor and Outdoor Allergies

*When taken as directed. See Drug Facts Panel.

TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.

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 right away.

Directions (24 Hour Relief)

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 BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**
- **Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]**
- **protect from excessive moisture**

Inactive Ingredients

Corn starch, lactose monohydrate and magnesium stearate.

Questions or comments?

1-800-848-0462

- Serious side effects associated with use of this product may be reported to this number.

Manufactured for:

Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Made in India

Code No.: MH/DRUGS/25/NKD/89

Distributed by:

Mylan Institutional Inc.
Rockford, IL 61103 U.S.A.

S-11333 R2

11/16

PRINCIPAL DISPLAY PANEL - 10 mg

NDC 51079-246-20

**Loratadine
Tablets, USP
10 mg**

Antihistamine

Original Prescription Strength Non-Drowsy*

Indoor and Outdoor Allergies

24 Hour Relief (See Uses section of enclosed leaflet)

*When taken as directed. See enclosed leaflet.

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NDC 51079-246-20

Loratadine
Tablets, USP

10 mg

Antihistamine



100 Tablets (10 x 10)

Drug Facts

<i>Active Ingredient (in each tablet)</i>	<i>Purpose</i>
Loratadine USP, 10 mg	Antihistamine

Uses See enclosed leaflet

Warnings See enclosed leaflet

Directions See enclosed leaflet

Other information ■ **TAMPER EVIDENT: DO NOT USE IF
BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS
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[See USP Controlled Room Temperature.] ■ protect from
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S- 11332 R2

UNIT-DOSE

- This unit dose package is not child resistant.
- For institutional use only.
- Keep this and all drugs out of the reach of children.
- This container provides light-resistance.
- See window for lot number and expiration date.



Mylan[®]

Distributed by:
Mylan Institutional Inc.
Rockford, IL 61103 U.S.A.



GTIN XXXXXXXXXXXXXXXX
SN XXXXXXXXXXXXXXXX
EXPMMYYT
LOT XXXXXXXX

LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51079-246
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
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white (white to off-white)	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	G;L;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51079-246-20	100 in 1 BOX, UNIT-DOSE	04/30/2013	01/31/2030
1	NDC:51079-246-01	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	ANDA076154	04/30/2013	01/31/2030

Labeler - Mylan Institutional Inc. (039615992)