

**LORATADINE- loratadine tablet**  
**Mylan Institutional Inc.**

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**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 R3

1/21

**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

*Original Prescription Strength*

**Non-Drowsy\***

Indoor and Outdoor Allergies

24 Hour Relief (See Uses section of 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 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.

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Made in India

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

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.



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



GTIN XXXXXXXXX  
SN XXXXXXXXX  
EXP MM YYYY  
LOT XXXXX

## **LORATADINE**

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51079-246(NDC:0378-8880)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>LORATADINE</b> (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	10 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>STARCH, CORN</b> (UNII: 08232NY3SJ)	
<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>	G;L;10
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51079-246-20	100 in 1 BOX, UNIT-DOSE	04/30/2013	
1	NDC:51079-246-01	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA076154	04/30/2013	

**Labeler** - Mylan Institutional Inc. (039615992)