LORATADINE- loratadine tablet
Mylan Pharmaceuticals Inc.

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

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 of kidney disease	ask a doctor

Other information

- Tamper Evident: do not use if foil seal under cap is missing, open or broken.
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

Inactive ingredients

Corn starch, lactose monohydrate and magnesium stearate.

Questions or comments?

call **1-877-446-3679 (1-877-4-INFO-RX)**

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Made in India
Code No.: MH/DRUGS/25/NKD/89

PRODUCT PACKAGING

NDC 0378-8880-10

Original Prescription Strength

Non-Drowsy*

Loratadine
Tablets USP, 10 mg

Antihistamine

Indoor and Outdoor Allergies

24 Hour Relief of:

- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**
- **Itchy Throat or Nose**

***When taken as directed. See Drug Facts Panel.**

RMX8880C1

100 Tablets

NDC 0378-8880-10

Original Prescription Strength

Non-Drowsy*

Loratadine

Tablets, USP **10 mg**

Antihistamine
Indoor and Outdoor Allergies

24 Hour Relief of: ■ *Sneezing* ■ *Runny Nose* ■ *Itchy, Watery Eyes* ■ *Itchy Throat or Nose*

*When taken as directed. See Drug Facts Panel.

Mylan®

RMX8880C1 1000 Tablets

Drug Facts

Active Ingredient (in each tablet)	Purpose
Loratadine USP, 10 mg	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 ▶

OPEN FOR FULL LABELING

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
Made in India
Code No.: MH/DRUGS/25/NKD/89

Drug Facts (continued)

Warnings

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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.

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Drug Facts (continued)

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Directions

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children under 6 years of age	ask a doctor
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NDC 0378-8880-10

Original Prescription Strength

Non-Drowsy*

Loratadine

Tablets, USP **10 mg**

Antihistamine
Indoor and Outdoor Allergies

24 Hour Relief of: ■ *Sneezing* ■ *Runny Nose* ■ *Itchy, Watery Eyes* ■ *Itchy Throat or Nose*

*When taken as directed. See Drug Facts Panel.

Mylan®

RMX8880C1 1000 Tablets

Drug Facts (continued)

Other information

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Made in India
Code No.: MH/DRUGS/25/NKD/89

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Lot
Exp.

NO VARNISH ZONE

LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0378-8880
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**
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:0378-8880-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076154	06/01/2011	

Labeler - Mylan Pharmaceuticals Inc. (059295980)

Revised: 11/2013 Mylan Pharmaceuticals Inc.