LORATADINE- loratadine tablet
Medline Industries, Inc.

Drug Facts

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 or kidney disease	ask a doctor

OTHER INFORMATION

- store between 20 and 25° C (68 and 77° F)
- protect from excessive moisture
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**

INACTIVE INGREDIENTS

Corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

QUESTIONS?

Call **1-800-MEDLINE (633-5463), Monday - Friday, 9AM - 5PM CST**

PRINCIPAL DISPLAY PANEL

MEDLINE

NDC 53329-651-33

†**Compare to the active ingredient in Claritin®**

NON-DROWSY*

LORATADINE TABLETS, USP 10 mg

ANTIHISTAMINE

ALLERGY RELIEF

Indoor & Outdoor Allergies

24 HOUR RELIEF of:

• Sneezing

• Runny Nose

• Itchy, Watery Eyes

• Itchy Throat or Nose

10 mg

30 Tablets

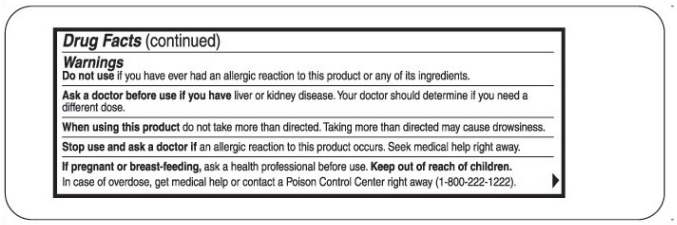
(When taken as directed. See Drug Facts Panel.)

Distributed by: Medline, Industries, Inc.

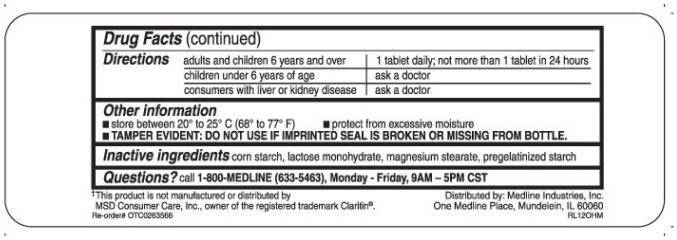
5099016/1012

TOP LABEL

INSIDE TOP LABEL



BASE LABEL



LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53329-651
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)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white (White to Off-White)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	RX526
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53329-651-33	30 in 1 BOTTLE		

2	NDC:53329-651-38	90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076134	08/19/2003	

Labeler - Medline Industries, Inc. (025460908)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(53329-651)

Revised: 3/2013 Medline Industries, Inc.