LORATADINE- loratadine tablet Cardinal Health

Drug Facts

Original Prescription Strength Non-Drowsy

Indoor and Outdoor Allergies

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)

	1 tablet daily; not more
6 years and over	than 1 tablet in 24 hours
children under 6 years of age	ask a doctor
consumers with liver	ask a doctor
or kidney disease	

Other information

- TAMPER EVIDENT: DO NOTUSE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

Inactive ingredients

Anhydrous lactose, colloidal silicon dioxide, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, povidone and sodium lauryl sulfate.

Questions or comments?

1-800-848-0462

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

Manufactured by:

Mylan Pharmaceuticals Inc.

Morgantown, WV 26505 U.S.A.

Distributed by:

UDL Laboratories, Inc.

Rockford, IL 61103

S-10314 R1

7/11

Principal Display Panel

Loratadine Tablets, USP

10 mg

Antihistamine

10 Tablets



T81

LORATADINE TABLETS, USP 10 mg

Antihistamine

10 TABLETS

Indoor and Outdoor Allergies

Original Prescription Strength Non-Drowsy* *When taken as directed. See product insert. 24 Hour Relief (See Uses section of product insert) Drug Facts

Active Ingredient (in each tablet)

Purpose Antihistamine

Loratadine USP, 10 mg

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See product insert for uses, warnings, directions, prescribing information and precautions

STORAGE: Store between 20 to 25 C (68 to 77 F) protect from excessive moisture

WARNING: This package is intended for institutional use only. Keep this and all drugs out of the reach of children. This unit dose package is not child resistant.

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

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

Packaged and Distributed by: UDL LABORATORIES, INC. ROCKFORD, IL 61103

Repackaged by Cardinal Health Zanesville, OH 43701 L43308090112

LOT #: XXXX

EXP. DATE: 12/34

LORATADINE

loratadine tablet

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Pro	duct	Inforn	nation
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HUMAN OTC DRUG Product Type LABEL

Item Code (Source)

NDC:55154-5099(NDC:51079-538)

Route of Administration

ORAL

DEA Schedule

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Active	Ingred	tient/A	ctive	Moiety

Ingredient Name	Basis of Strength	Strength

LORATADINE (LORATADINE)

LORATADINE

10 mg

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS LACTOSE		
SILICON DIO XIDE		
STARCH, CORN		
HYPROMELLOSES		
MAGNESIUM STEARATE		
CELLULO SE, MICRO CRYSTALLINE		
POVIDONES		
SO DIUM LAURYL SULFATE		

Product Characteristics			
Color	WHITE (white to off-white)	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	M;L;17
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-5099-0	10 in 1 BAG		
1		1 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075790	11/19/2009	

Labeler - Cardinal Health (188557102)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cardinal Health		188557102	REPACK(55154-5099)	

Revised: 3/2013 Cardinal Health