LEADER LORATADINE- loratadine tablet
Cardinal Health

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

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

INACTIVE INGREDIENTS

corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

QUESTIONS?

call **1-800-406-7984**

Keep the carton. It contains important information.

See end panel for expiration date.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL.

NDC 37205-346-52

LEADER®

Compare to Claritin® active ingredient†

Non-Drowsy*

ORIGINAL PRESCRIPTION STRENGTH

Loratadine

Loratadine Tablets USP, 10 mg/Antihistamine

Indoor & Outdoor Allergies

24 Hour Allergy Relief

Relief of:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

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

10 TABLETS

†**This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., owner of the registered trademark Claritin®.**

10's Blister Carton

90's Bottle Carton

LEADER LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-346
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:37205-346-52	10 in 1 BLISTER PACK		
2	NDC:37205-346-60	20 in 1 BLISTER PACK		
3	NDC:37205-346-65	30 in 1 BLISTER PACK		
4	NDC:37205-346-72	60 in 1 BOTTLE		
5	NDC:37205-346-75	90 in 1 BOTTLE		
6	NDC:37205-346-47	150 in 1 BOTTLE		

Marketing Information

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

Labeler - Cardinal Health (097537435)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(37205-346)

Revised: 3/2012 Cardinal Health