LORATADINE ODT- loratadine tablet, orally disintegrating Shopko Stores Operating Co., LLC

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 (1-800-222-1222).

DIRECTIONS

• place 1 tablet on tongue; tablet disintegrates, with or without water

1 tablet daily; not more than 1 tablet in 24 hours			
ask a doctor			
consumers with liver or kidney disease ask a doctor			

OTHER INFORMATION

- Phenylketonurics: Contains Phenylalanine 0.6 mg Per Tablet.
- TAMPER EVIDENT: DO NOT USE 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.
- keep in a dry place.
- use tablet immediately after opening individual blister.

INACTIVE INGREDIENTS

Aspartame, croscarmellose sodium, magnesium stearate, mannitol, mint flavor, sodium stearyl fumarate, strawberry cream flavor, tutti-frutti flavor

QUESTIONS?

Call 1-800-406-7984

PRINCIPAL DISPLAY PANEL

SHOPKO[®]

[†]Compare to the Active Ingredient of Claritin[®]RediTabs[®]

Original Prescription Strength

Allergy Relief

Loratadine Orally Disintegrating Tablets, USP 10 mg

Antihis tamine

Non-Drowsy*

Indoor & Outdoor Allergies

24 Hour Allergy Relief

For Adults and Children six years and older!

Relief of: Sneezing, Runny Nose, Itchy/Watery Eyes, Itchy Throat or Nose

· No Water Needed · Melts in Your Mouth

Manufactured by: Ohm Laboratories Inc.

5093689/R0512

^{*}When taken as directed. See Drug Facts Panel.



Drug Facts (continued)

Manufactured by: Ohm Laboratories Inc. 1385 Livingston Avenue North Brunswick, NJ 08902

LORATADINE ODT

loratadine tablet, orally disintegrating

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37012-527

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	Zuoio di Guicingui	o trength
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg

Inactive Ingredients Ingredient Name Strength ASPARTAME (UNII: Z0H242BBR1) CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) MAGNESIUM STEARATE (UNII: 70097M6I30) MANNITOL (UNII: 3OWL53L36A) SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)

Product Characteristics			
Color	white (White to Off-White)	Score	no score
Shape	ROUND (Flat Faced Beveled Edge)	Size	10 mm
Flavor	MINT, STRAWBERRY, TUTTI FRUTTI	Imprint Code	RC17
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:37012-527-31	30 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077153	08/31/2007	

Labeler - Shopko Stores Operating Co., LLC (023252638)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(37012-527)

Revised: 3/2013

Shopko Stores Operating Co., LLC