### LORATADINE ODT- loratadine tablet, orally disintegrating Chain Drug Consortium, LLC

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**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

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

#### 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, fruit flavors, magnesium stearate, mannitol, sodium stearyl fumarate

#### **QUESTIONS?**

call 1-800-406-7984

Keep the carton. It contains important information.

See end panel for expiration date.

**DISTRIBUTED BY** 

CHAIN DRUG CONSORTIUM

3301 NW BOCA RATON BLVD

SUITE 101, BOCA RATON, FL 33431

#### PRINCIPAL DISPLAY PANEL

**Premier Value**®

NDC 68016-527-31

**Original Prescription Strength** 

**NON-DROWSY\*** 

24 Hour Allergy Relief

Loratadine Orally Disintegrating Tablets, 10 mg

**Allergy Relief** 

**Antihis tamine** 

**Indoor & Outdoor Allergies** 

No water needed. Melts in your mouth.

#### Relief of:

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

For Adults and Children six years and older! 30 ORALLY DISINTEGRATING TABLETS COMPARE TO THE ACTIVE INGREDIENT OF CLARITIN  $^{\rm @}$  REDITABS  $^{\rm @}$  †

<sup>\*</sup>When taken as directed. See Drug Facts Panel.

 $<sup>^\</sup>dagger T$ his product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc. CLARITIN $^{\$}$  and REDITABS $^{\$}$  are registered trademarks of Schering Corporation.



■ TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING. ■ Phenylketonutics: Contains Phenylalanine 0.6 mg Per Tablet.

#### Other information

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

■ biace 1 tablet on tongue; tablet disintegrates, with or without water Directions

right away (1-800-222-1222).

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

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

When using this product do not take more than directed. Taking more than directed may cause

different dose. Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a

Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

■ itching of the nose or throat 6uizeeus ■ піспу, мателу еуеѕ USES temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

Loratadine, USP 10 mg. Purpose

Active ingredient (in each tablet)

Drug Facts









NDC 68016-527-31 COMPARE TO THE ACTIVE

INGREDIENT OF CLARITIN® REDITABS®† **Original Prescription Strength** NON-DROWSY\*

24 Hour Allergy Relief





**Antihistamine** 

✓ Sneezing ✓ Itchy, Watery Eyes ✓ Runny Nose ✓ Itchy Throat or Nose

Relief of:

Loratadine Orally Disintegrating Tablets, USP 10 mg

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Indoor & Outdoor Allergies No Water Needed . Melts in Your Mouth

For Adults and

Children six years and older!



Keep the carton. It contains important information. See end panel for expiration date.

Expiration Date

Batch

Non Varnish Area

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#### **ORALLY DISINTEGRATING TABLETS** When taken as directed. See Drug Facts Panel.



sodium stearyl fumarate, strawberry cream flavor, tutti-frutti flavor Inactive ingredients aspartame, croscarmellose sodium, magnesium stearate, mannitol, mint flavor,

- use tablet immediately after opening individual blister.
  - keep in a dry place.
- store between 20° to 25° C (68° to 77° F). Protect from excessive moisture.

Drug Facts (continued)

# DISTRIBUTED BY CHAIN DRUG CONSORTIUM 3301 NW BOCA RATON BLVD SUITE 101, BOCA RATON, FL 33431 PRE84057B08



#### LORATADINE ODT

loratadine tablet, orally disintegrating

Droduct	Information
Product	THIOT HIALIOH

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-527

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

ı	8		
ı	Ingredient Name	Basis of Strength	Strength
ı	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	STRAWBERRY, TUTTI FRUTTI, MINT	Imprint Code	RC17
Contains			

	Packaging				
# Item Code Package Description		<b>Marketing Start Date</b>	Marketing End Date		
l	1	NDC:68016-527-31	30 in 1 BLISTER PACK; Type 0: Not a Combination Product		

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

#### Labeler - Chain Drug Consortium, LLC (101668460)

#### Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

#### **Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	MANUFACTURE(68016-527)

Revised: 10/2015 Chain Drug Consortium, LLC