LORATADINE ODT- loratadine tablet, orally disintegrating Meijer Distribution, 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 (1-800-222-1222).

DIRECTIONS

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

ladilite and enlidren 6 Vears 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

- 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

PRINCIPAL DISPLAY PANEL

NDC 41250-527-31

Compare to Claritin[®] Reditabs[®] active ingredient**

meijer_{TM}

Original Prescription Strength

Non-Drowsy*

24 HOUR RELIEF

Allergy Relief

Loratadine Orally Disintegrating Tablets, 10 mg · Antihistamine

For Adults and Children six years and older!

No Water Needed · Melts in Your Mouth!

Indoor & Outdoor Allergies

For 24 Hour Relief of:

sneezing; runny nose;

itchy, watery eyes; itchy throat or nose

*When taken as directed.

See Drug Facts Panel.

30 ORALLY DISINTEGRATING TABLETS

DIST.BY MEIJER DISTRIBUTION, INC.

5078746/R0410



Compare to ALAVERT $^{\text{@}}$ active ingredient **

meijerTM

Original Prescription Strength

Non-Drowsy*

24 HOUR RELIEF

Allergy Relief

Loratadine Orally Disintegrating Tablets, 10 mg • Antihistamine

For Adults and Children six years and older!

Mint Flavored

No Water Needed · Melts in Your Mouth!

For 24 Hour Relief of:

sneezing; runny nose;

itchy, watery eyes; itchy throat or nose

Indoor & Outdoor Allergies

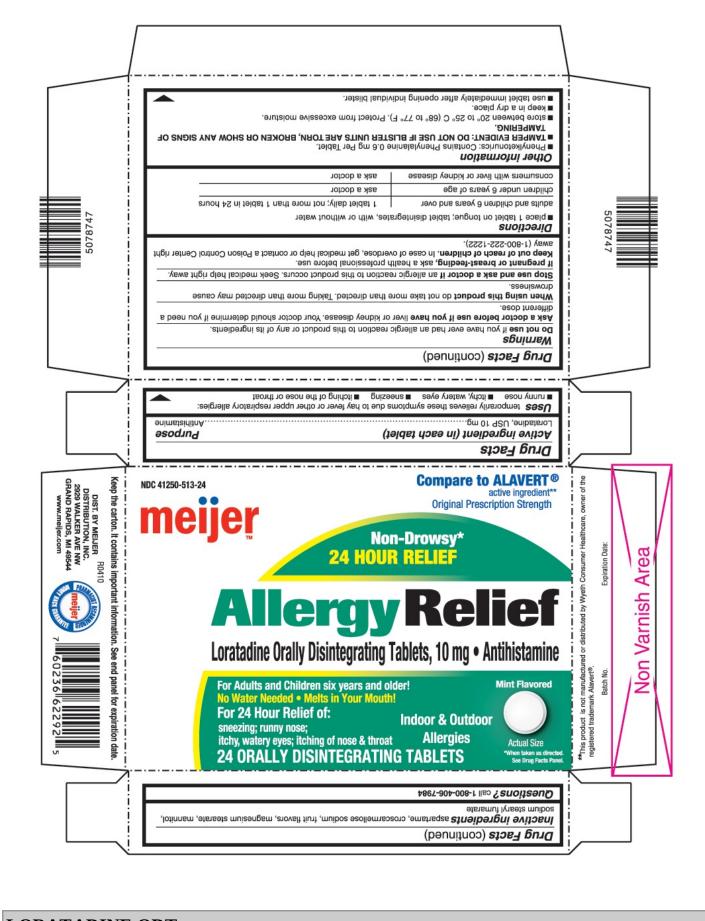
24 ORALLY DISINTEGRATING TABLETS

*When taken as directed.

See Drug Facts Panel.

DIST.BY MEIJER DISTRIBUTION, INC.

5078747/R0410



LORATADINE ODT

loratadine tablet, orally disintegrating

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-527	
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
ASPARTAME (UNII: Z0H242BBR1)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
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	FRUIT	Imprint Code	RC17
Contains			

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-527-31	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	

LORATADINE ODT

loratadine tablet, orally disintegrating

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-513
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

LORATADINE ((UNII: 7AJO3BO70	QN) (LORATADINE - U	UNII:7AJO3BO7ON)
LOIGITIDE ((OITH, /IBOBBO/C	QII) (ECIGIIIIEII)	C11H.71B C B B C 7 Q 11)

LORATADINE

10 mg

mactive ingredients	
Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CODUM CEPADAL FUMADATE (UNII, 7CV/25/11/4/11)	

P	rod	luct	Charac	cteristics
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1 Todact Characteristics			
Color	white (White to Off-White)	Score	no score
Shape	ROUND (Flat Faced Beveled Edge)	Size	10 mm
Flavor	FRUIT	Imprint Code	RC17
Contains			

Packaging

ı				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:41250-513-24	24 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 - Meijer Distribution, Inc. (006959555)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment					
Name	Address	ID/FEI	Business Operations		
Ohm Laboratories Inc.		051565745	manufacture(41250-527)		

Revised: 9/2012 Meijer Distribution, Inc.