LORATADINE ODT- loratadine tablet, orally disintegrating
Topco Associates 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

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

- 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 **1-888-423-0139**

PRINCIPAL DISPLAY PANEL

Topcare®

NDC 36800-528-69

Ages 6 years and older

Children's MELT-IN-YOUR-MOUTH TABLETS. NO WATER NEEDED

Original Prescription Strength

24 HOUR NON-DROWSY*

Allergy Relief

LORATADINE ORALLY DISINTEGRATING TABLETS, USP 10 mg

ANTIHISTAMINE

Indoor & Outdoor Allergies

For 24 Hour Relief of:

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

COMPARE TO CLARITIN® REDITABS® active ingredient†

10 ORALLY DISINTEGRATING TABLETS

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

DISTRIBUTED BY TOPCO ASSOCIATES LLC

5095193/R812

Drug Facts (continued)

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

Questions? call **1-888-423-0139**

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

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actual size

COMPARE TO CLARITIN® REDITABS® active ingredient†

10 ORALLY DISINTEGRATING TABLETS

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This TOP CARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
1-888-423-0139 ©TOPCO OHMR812
topcare@topco.com

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Batch No.

Expiration Date:

Non Varnish Area

Drug Facts

Active ingredient (in each tablet)	Purpose
Loratadine, USP 10 mg	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

Drug Facts (continued)

Warnings

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5095193

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LORATADINE ODT

loratadine tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:36800-528
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (LORATADINE)	LORATADINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME	
CROSCARMELLOSE SODIUM	
MAGNESIUM STEARATE	
MANNITOL	
SODIUM STEARYL FUMARATE	

Product Characteristics

Color	white (white to off white)	**Score**	no score
Shape	ROUND (flat faced beveled edge)	**Size**	10mm
Flavor	STRAWBERRY, TUTTI FRUTTI, MINT	**Imprint Code**	RC17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-528-69	10 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 - Topco Associates LLC (006935977)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(36800-528)