

LORATADINE- loratadine tablet, orally disintegrating
Topcare 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 36800-527-69

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 Adults and Children six years and older!

For 24 Hour Relief of:

- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**
- **Itching 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

5095192/R812

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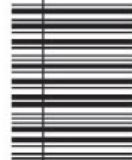
Drug Facts (continued)

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.
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).

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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
■ Phenylephrine: Contains Phenylephrine 0.6 mg Per Tablet.
■ **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**
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5095192



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

Purpose
Antihistamine

Uses
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
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actual size

10 ORALLY DISINTEGRATING TABLETS

COMPARE TO CLARITIN® REDITABS® active ingredient†

QUALITY GUARANTEED

*When taken as directed. See Drug Facts Panel.

QUALITY GUARANTEED
The TOPCARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

DIST. BY TOPCO ASSOCIATES, LLC
7711 GROSS POINT ROAD
SKOKIE, IL 60077 ©TOPCO OHM408
QUESTIONS? 1-888-423-0139
topcare@topco.com

OHMR812 0 36800 08395 0

Drug Facts (continued)

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

Questions? call 1-800-406-7984

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

† This product is not manufactured or distributed by Schering-Plough Healthcare Products, Inc. CLARITIN® and REDITABS® are registered trademarks of Schering Corporation.

Batch No. Expiration Date:

Non Varnish Area

LORATADINE

loratadine tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-527
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: 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	10mm
Flavor	STRAWBERRY, TUTTI FRUTTI, MINT	Imprint Code	RC17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-527-69	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 - Topcare Associates LLC (006935977)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(36800-527)

Revised: 8/2012

Topcare Associates LLC