LORATADINE- loratadine tablet, orally disintegrating
American Sales Company

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

QUESTIONS?

Call **1-800-406-7984**

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient of Alavert®†

CAREONE®

Original Prescription Strength

Non-Drowsy*

24 hour

ALLERGY RELIEF

Loratadine Orally Disintegrating Tablets, 10 mg/Antihistamine

Indoor & Outdoor Allergies

NO WATER NEEDED · MELTS IN YOUR MOUTH

FOR ADULTS AND CHILDREN SIX YEARS AND OLDER!

Relief of:

- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**
- **Itching of Nose & Throat**

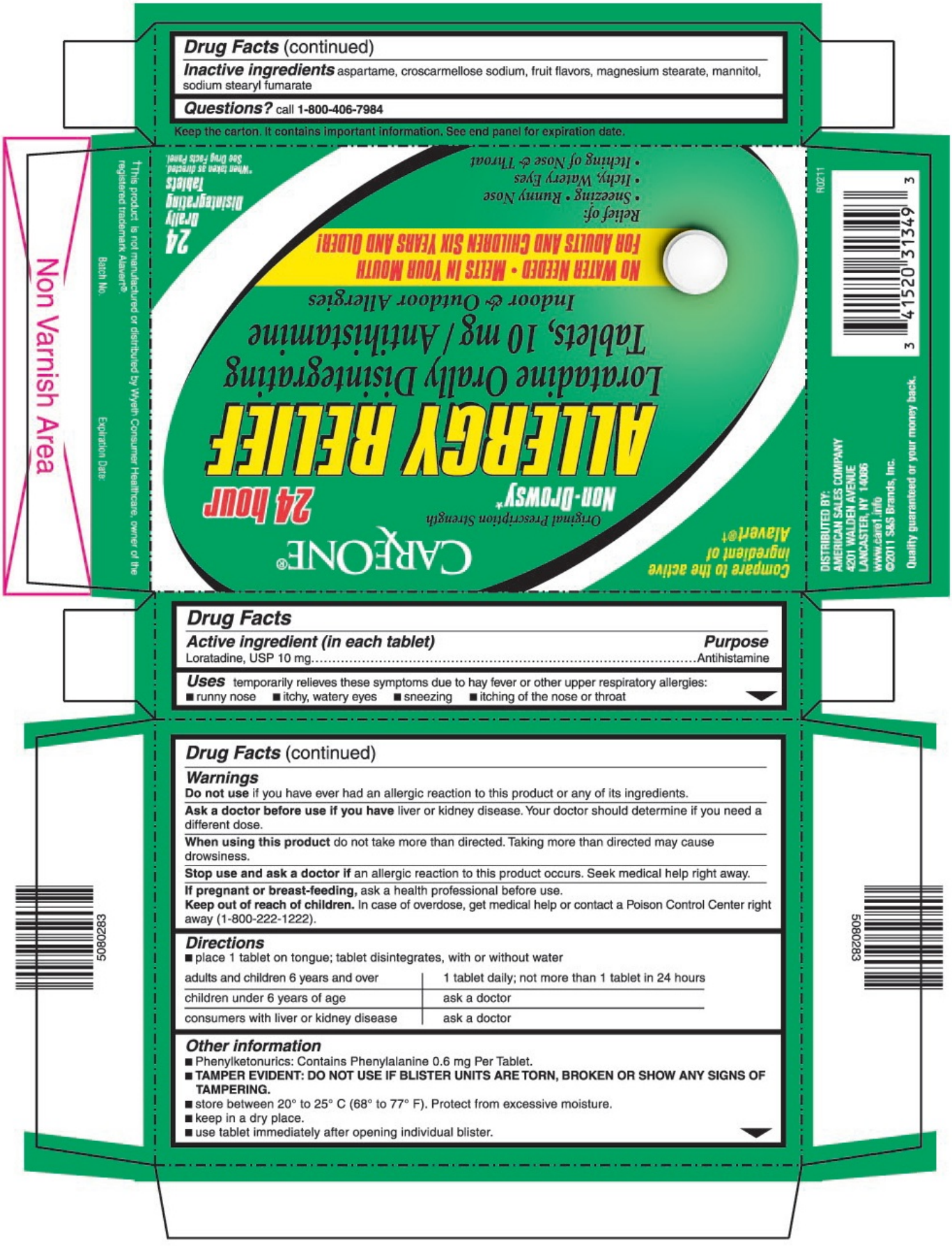
24 Orally Disintegrating Tablets

***When taken as directed.**

See Drug Facts Panel.

DISTRIBUTED BY: AMERICAL SALES COMPANY

5080283/R0211


Drug Facts (continued)
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.
Non Varnish Area
†This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Alavert®.
Batch No.
Expiration Date
24 Orally Disintegrating Tablets
*When taken as directed. See Drug Facts Panel.
NO WATER NEEDED • MELTS IN YOUR MOUTH
FOR ADULTS AND CHILDREN SIX YEARS AND OLDER!
Relief of:
• Sneezing • Runny Nose
• Itchy, Watery Eyes
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Indoor & Outdoor Allergies
Loratadine Orally Disintegrating Tablets, 10 mg / Antihistamine
ALLERGY RELIEF
24 HOUR
Original Prescription Strength
NON-DROWSY*
CARE ONE®
Compare to the active ingredient of Alavert®†
DISTRIBUTED BY:
AMERICAN SALES COMPANY
4201 WALDEN AVENUE
LANCASTER, NY 14086
www.care1.info
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Quality guaranteed or your money back.
R0211
3 41520 31349 3
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)
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LORATADINE

loratadine tablet, orally disintegrating

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-513
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	FRUIT	**Imprint Code**	RC17
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:41520-513-24	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 - American Sales Company (809183973)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(41520-513)