LORATADINE ODT - loratadine tablet, orally disintegrating
Rugby Laboratories

Loratadine Orally Disintegrating Tablets USP 10 mg

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
- sneezing
- itchy, watery eyes
- 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 (1-800-222-1222) right away.

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 2.25 mg per tablet
- do not use if the individual blister unit is open or torn
- store at 20° to 25°C (68° to 77°F)
- use tablet immediately after opening individual blister
- Complies with USP test 2 for Disintegration

Inactive ingredients

aspartame, crospovidone, mannitol, microcrystalline cellulose, peppermint, pregelatinized starch (maize), sodium stearyl fumarate

Questions or comments?

call **1-800-616-2471**

Distributed by:
RUGBY® LABORATORIES
Indianapolis, IN 46268
www.majorpharmaceuticals.com

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg, Blister Carton 30 (3 X 10) Orally Disintegrating Tablets

Rugby®

NDC 0536-1367-07
Compare to the
active ingredient in
Claritin® RediTabs®**

Original Prescription Strength
Non-Drowsy*
Loratadine Orally Disintegrating
Tablets USP
10 mg

Antihistamine

Indoor & Outdoor Allergies

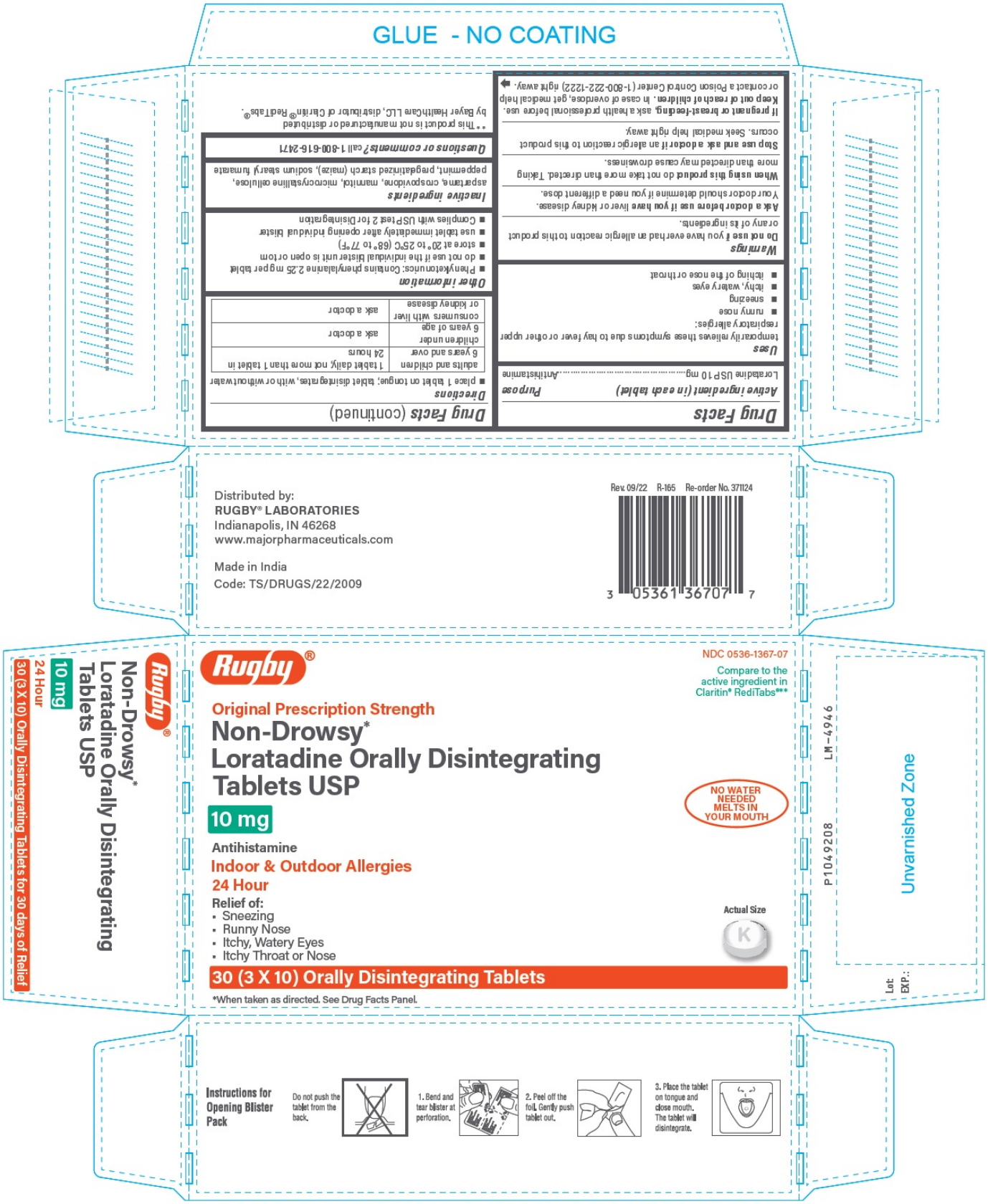
24 Hour

NO WATER
NEEDED
MELTS IN
YOUR MOUTH

Relief of:
• Sneezing
• Runny Nose
• Itchy, Watery Eyes
• Itchy Throat or Nose

30 (3 X 10) Orally Disintegrating Tablets

*When taken as directed. See Drug Facts Panel.



LORATADINE ODT

loratadine tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1367
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)	
CROSPOVIDONE (120 .MU.M) (UNII: 68401960MK)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PEPPERMINT (UNII: V95R5KMY2B)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics

Color	WHITE (White to Off-white)	**Score**	no score
Shape	ROUND (Biconvex)	**Size**	8mm
Flavor	PEPPERMINT	**Imprint Code**	K;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1367-07	3 in 1 CARTON	10/06/2022	
1		10 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	ANDA208477	10/06/2022	

Labeler - Rugby Laboratories (079246066)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(0536-1367) , MANUFACTURE(0536-1367)

Revised: 10/2022

Rugby Laboratories