

LORATADINE - loratadine tablet
Major Pharmaceuticals

Loratadine 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
- 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 (1-800-222-1222) right away.

Directions

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

- Tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken
- store at 20° to 25°C (68° to 77°F)
- protect from excessive moisture

Inactive ingredients

lactose monohydrate, magnesium stearate, pregelatinized starch (maize), sodium starch glycolate.

Questions or comments?

call **1-855-274-4122**

Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

www.majorpharmaceuticals.com

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (30 Tablets Bottle)

MAJOR®

NDC 0904-7426-46

Non-Drowsy*
Loratadine Tablets USP
10 mg
Antihistamine

24 Hour | Indoor & Outdoor Allergies

Relief of:

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

30 Tablets

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

<p>MAJOR® NDC 0904-7426-46</p> <p>Non-Drowsy* Loratadine Tablets USP 10 mg Antihistamine</p> <p>24 Hour Indoor & Outdoor Allergies</p> <p>Relief of: • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose</p> <p>30 Tablets</p> <p><small>*When taken as directed. See Drug Facts Panel.</small></p>	<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Loratadine USP 10 mg.....Antihistamine</p> <p>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</p> <p>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.</p> <p>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.</p> <p>Directions ■ 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</p> <p>Other information ■ Tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken ■ store at 20° to 25°C (68° to 77°F) ■ protect from excessive moisture</p> <p>Inactive ingredients lactose monohydrate, magnesium stearate, pregelatinized starch (maize), sodium starch glycolate.</p> <p>Questions or comments? call 1-855-274-4122</p> <p>Distributed by: MAJOR•PHARMACEUTICALS Indianapolis, IN 46268 (800) 616-2471 www.majorpharmaceuticals.com Rev. 01/24 M-165 Re-order No. 701385</p>	<p>P1433800 LM-5489</p> <p>Unvarnished Zone (dotted line not for printing) 28.5 x 13 mm</p>
---	--	--

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg Container Carton (30 Tablets)

MAJOR®

NDC 0904-7426-46
Compare to the
active ingredient
in Claritin®†

Non-Drowsy*
Loratadine
Tablets USP
10 mg
Antihistamine

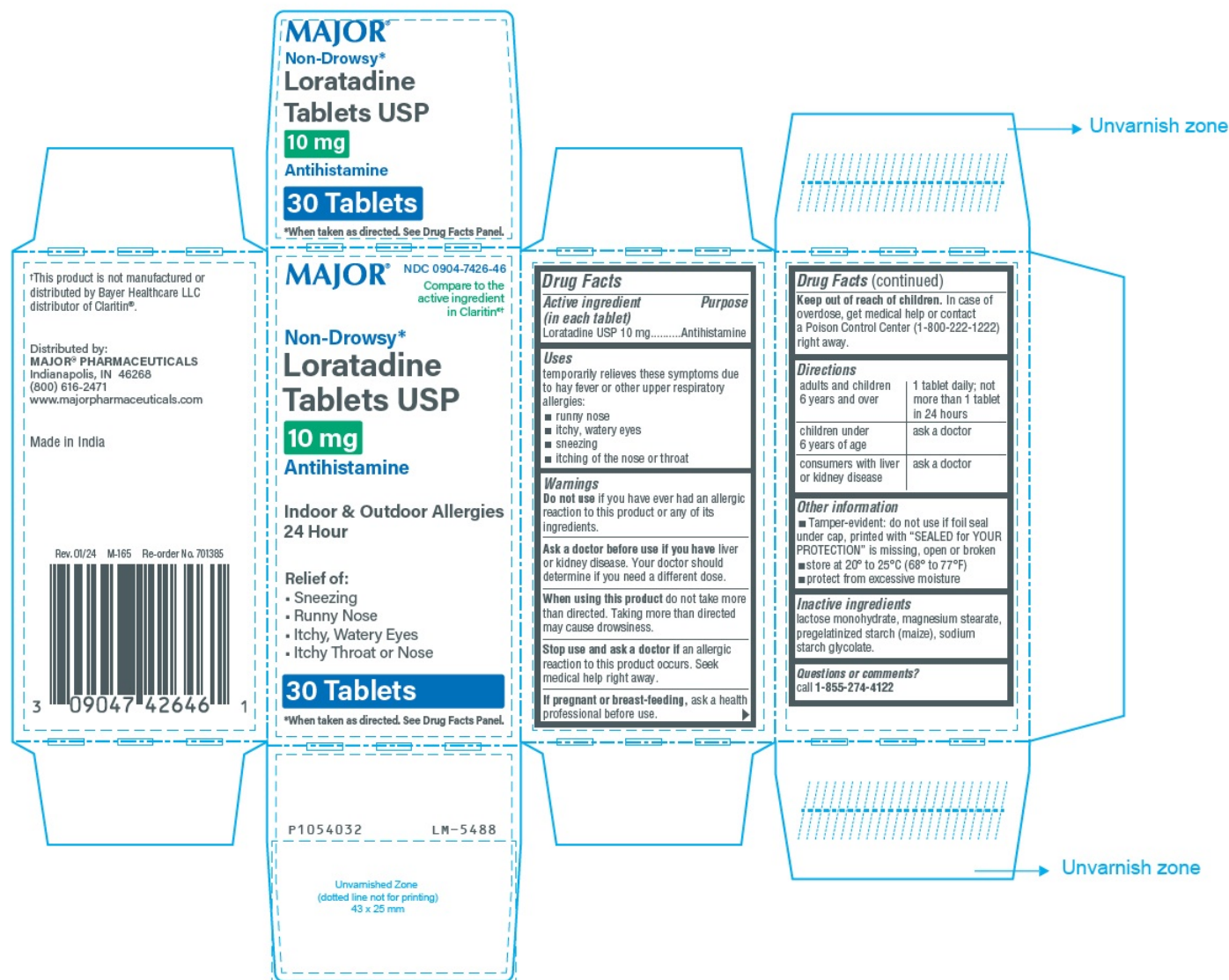
Indoor & Outdoor Allergies
24 Hour

Relief of:

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

30 Tablets

*When taken as directed. See Drug Facts Panel.



LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7426
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)		LORATADINE	10 mg	
Inactive Ingredients				
Ingredient Name			Strength	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
STARCH, CORN (UNII: O8232NY3SJ)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	WHITE (White to Off-white)	Score	no score	
Shape	ROUND	Size	6mm	
Flavor		Imprint Code	39;L	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7426-46	1 in 1 CARTON	02/23/2024	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0904-7426-59	1 in 1 CARTON	02/23/2024	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA208314		02/23/2024	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(0904-7426) , MANUFACTURE(0904-7426)