#### LORATADINE - loratadine tablet KROGER COMPANY

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**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	ask a doctor	
disease	dsk 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?

1-800-632-6900 DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202 MADE IN INDIA

Code: TS/DRUGS/22/2009

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

NDC 30142-066-09 Kroger® Non-Drowsy\* Allergy Relief 24 HOUR

# Loratadine Tablets USP 10 mg/Antihistamine

INDOOR & OUTDOOR
ALLERGIES
\*When taken as directed. See Drug Facts Panel.
RELIEF OF:
Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

#### 30 TABLETS



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

COMPARE TO the active ingredient of CLARITIN® TABLETS \*\*See bottom panel

NDC 30142-066-09

Kroger<sup>®</sup>

Non-Drowsy\*

Allergy Relief

Loratadine Tablets USP 10 mg/Antihistamine

INDOOR & OUTDOOR ALLERGIES
RELIEF OF: Sneezing; Runny Nose

Itchy, Watery Eyes; Itchy Throat or Nose

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

24 HOUR

actual size

L

#### 30 TABLETS



#### **LORATADINE**

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-066
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		
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			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:30142-066- 09	1 in 1 CARTON	03/15/2021		
1		30 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:30142-066- 54	1 in 1 CARTON	03/15/2021		
2		70 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	03/15/2021	

## Labeler - KROGER COMPANY (006999528)

## Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(30142-066), MANUFACTURE(30142-066)

Revised: 4/2021 KROGER COMPANY