

**LORATADINE - loratadine tablet**  
**McLane Company, Inc.**

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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 disease	ask a doctor

**Other information**

- safety sealed: do not use if the individual blister unit is open or torn
- 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:

**Consumer Value Products, Inc.**  
PO Box 6115, Temple Texas 76502  
CVPproducts.com

Made in India

Code: TS/DRUGS/22/2009

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg Blister Carton (10 Tablets)**

**NDC 57243-200-69**

**COMPARE TO**

**THE ACTIVE INGREDIENT**

**IN CLARITIN®**

CVP HEALTH

**NON-DROWSY\* . 24 Hour**

**ALLERGY RELIEF**

**LORATADINE TABLETS USP 10 mg**

ANTIHISTAMINE

INDOOR & OUTDOOR

ALLERGIES

**RELIEF OF:**

SNEEZING

RUNNY NOSE

ITCHY, WATERY EYES

ITCHY THROAT OR NOSE

**10 Tablets**

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

LEBG863B

NO COATING

NO COATING

**Drug Facts** (continued)

**Active ingredient(s) in each tablet:** Loratadine USP 10 mg. **Purpose:** Anti-itch medicine.

**Uses:** Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, runny nose, itchy, watery eyes, itchy throat or nose.

**Warnings:** Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

**Other information:** If you are taking other medicines, ask your doctor or pharmacist if there are any interactions.

**Directions:** Adults and children 12 years and over: 1 tablet orally once daily. Children 6 years and over: 1 tablet orally once daily. Children 2 to 5 years: 5 mg orally once daily.

**Drug Facts** (continued)

**Keep out of reach of children.** In case of overdose, get medical help or contact Poison Control Center at (1-800-222-1222) right away.

**Do not use if you have ever had an allergic reaction to this product or any of its ingredients.**

**Other information:** If you are taking other medicines, ask your doctor or pharmacist if there are any interactions.

**Directions:** Adults and children 12 years and over: 1 tablet orally once daily. Children 6 years and over: 1 tablet orally once daily. Children 2 to 5 years: 5 mg orally once daily.



NON-DROWSY\* • 24 HOUR  
**ALLERGY RELIEF**  
LORATADINE TABLETS USP 10 mg

LM-3135

NDC 57243-200-69

NON-DROWSY\* • 24 HOUR  
**ALLERGY RELIEF**  
LORATADINE TABLETS USP 10 mg

ANTIHISTAMINE  
INDOOR & OUTDOOR  
ALLERGIES

**10 TABLETS**

RELIEF OF:  
SNEEZING  
RUNNY NOSE  
ITCHY, WATERY EYES  
ITCHY THROAT OR NOSE

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

UNVARNISHED ZONE  
(Color/line art not to be printed)

Lat: \_\_\_\_\_  
Exp: \_\_\_\_\_

7 517 0 6115 543 4

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NON-DROWSY\* • 24 HOUR  
**ALLERGY RELIEF**  
LORATADINE TABLETS USP 10 mg

**LORATADINE**

loratadine tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57243-200
<b>Route of Administration</b>	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:57243-200-69	1 in 1 CARTON	04/16/2018	
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	ANDA208314	04/16/2018	

**Labeler** - McLane Company, Inc. (009830555)**Registrant** - Aurohealth LLC (078728447)**Establishment**

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(57243-200) , MANUFACTURE(57243-200)