LORATADINE - loratadine tablet
Aurohealth LLC

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: **AUROHEALTH LLC**
2572 Brunswick Pike
Lawrenceville, NJ 08648
Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (45 Tablets Bottle)

NDC 58602-702-17
Non-Drowsy*
Loratadine
Tablets USP 10 mg
Antihistamine

24 Hour
Relief of:
- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**
- **Itchy Throat or Nose**

Indoor & Outdoor
Allergies
***When taken as directed.**
See Drug Facts Panel. **45 Tablets**

* Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.

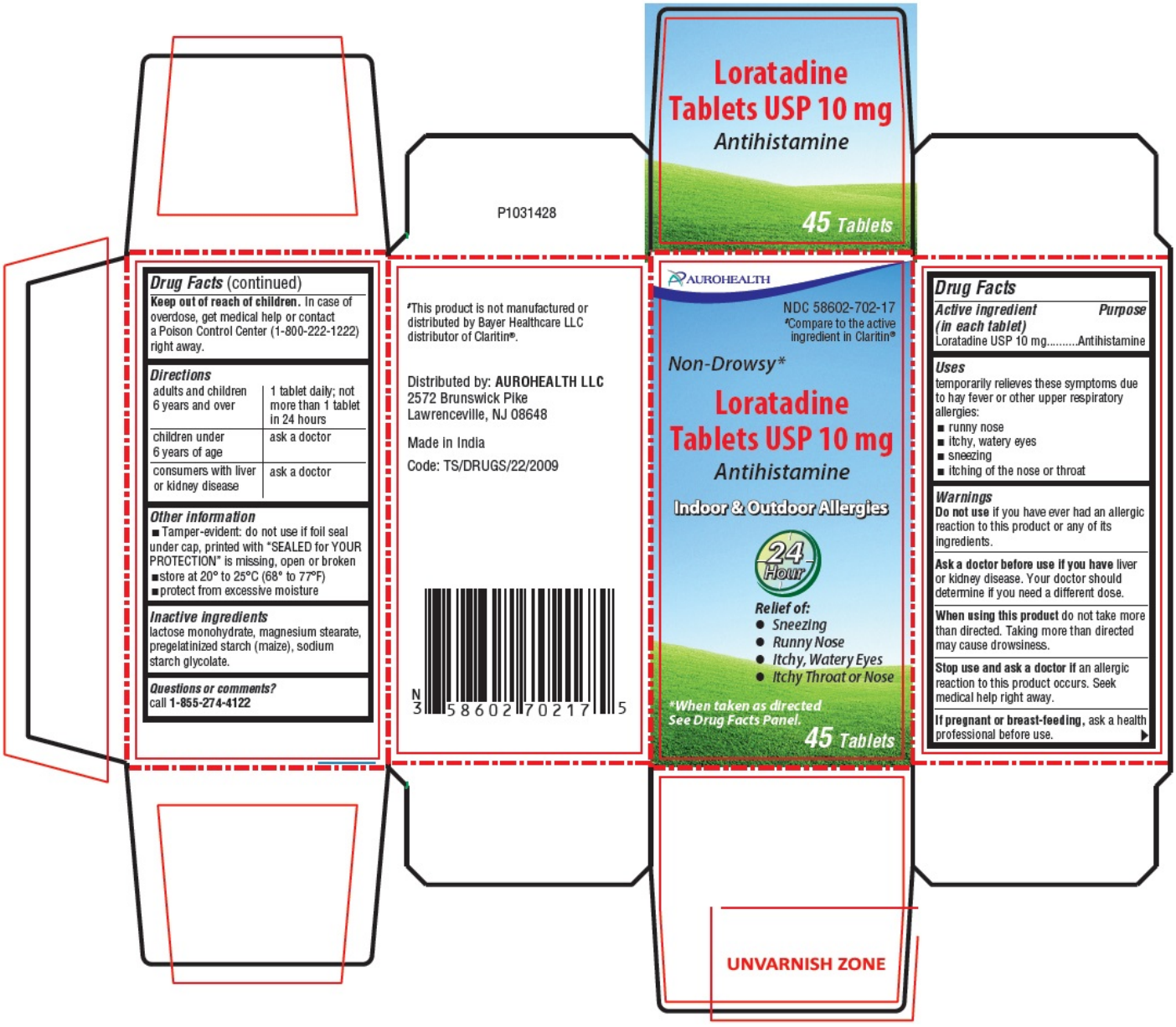
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg Container Carton (45 Tablets)

NDC 58602-702-17
#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**

***When taken as directed**
See Drug Facts Panel. **45 Tablets**



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

NDC 58602-702-84
#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**

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

Distributed by: AUROHEALTH LLC
2572 Brunswick Pike
Lawrenceville, NJ 08648
Made in India
Code: TS/DRUGS/22/2009

P1031438

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

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.

Drug Facts (continued)

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

*This product is not manufactured or distributed by Bayer Healthcare LLC distributor of Claritin®.

LEBG863B

LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-702
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			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58602-702-17	1 in 1 CARTON	04/16/2018	
1		45 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-702-15	1 in 1 CARTON	04/16/2018	
2		60 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-702-19	1 in 1 CARTON	04/16/2018	
3		90 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-702-81	1 in 1 CARTON	04/16/2018	
4		108 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-702-32	1 in 1 CARTON	04/16/2018	
5		180 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-702-60	1 in 1 CARTON	04/16/2018	
6		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:58602-702-83	1 in 1 CARTON	04/16/2018	
7		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

8	NDC:58602-702-67	2 in 1 CARTON	04/16/2018	
8		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
9	NDC:58602-702-84	3 in 1 CARTON	04/16/2018	
9		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
10	NDC:58602-702-05	5 in 1 CARTON	04/16/2018	
10		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:58602-702-09	1 in 1 CARTON	05/03/2019	
11		30 in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:58602-702-38	1 in 1 CARTON	05/03/2019	
12		300 in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:58602-702-39	1 in 1 CARTON	05/03/2019	
13		365 in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:58602-702-44	1 in 1 CARTON	07/26/2019	
14		400 in 1 BOTTLE; Type 0: Not a Combination Product		
15	NDC:58602-702-54	1 in 1 CARTON	10/04/2019	
15		70 in 1 BOTTLE; Type 0: Not a Combination Product		
16	NDC:58602-702-23	1 in 1 CARTON	10/04/2019	
16		120 in 1 BOTTLE; Type 0: Not a Combination Product		
17	NDC:58602-702-40	1 in 1 CARTON	11/28/2019	
17		500 in 1 BOTTLE; Type 0: Not a Combination Product		
18	NDC:58602-702-21	1 in 1 CARTON	12/23/2019	
18		100 in 1 BOTTLE; Type 0: Not a Combination Product		
19	NDC:58602-702-04	10 in 1 CARTON	02/10/2020	
19		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
20	NDC:58602-702-29	1 in 1 CARTON	08/13/2020	
20		150 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	04/16/2018	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-702) , MANUFACTURE(58602-702)