LORATADINE- loratadine tablet
BluePoint Laboratories

Loratadine Tablets USP 10mg

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 an 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°C 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**

Manufactured by: **Aurobindo Pharma Limited**

Hyderabad-509 302,

INDIA

For BluePoint Laboratories

MADE IN INDIA

Code: TS/DRUGS/22/2009

Issued: 04/2020

PACKAGE LABEL- PRINCIPAL DISPLAY PANEL - 10mg (100 Tablets Bottle)

NDC 68001-438-00

Non-Drowsy*

Loratadine

Tablets USP 10mg

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. 100 Tablets

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

NDC 68001-438-04

#Compare to the active ingredient in claritin®

Non-Drowsy*

Loratadine

Tablets USP 10mg

Antihisamine

Indoor and outdoor allergies

24 Hour

Relief of:

Sneezing

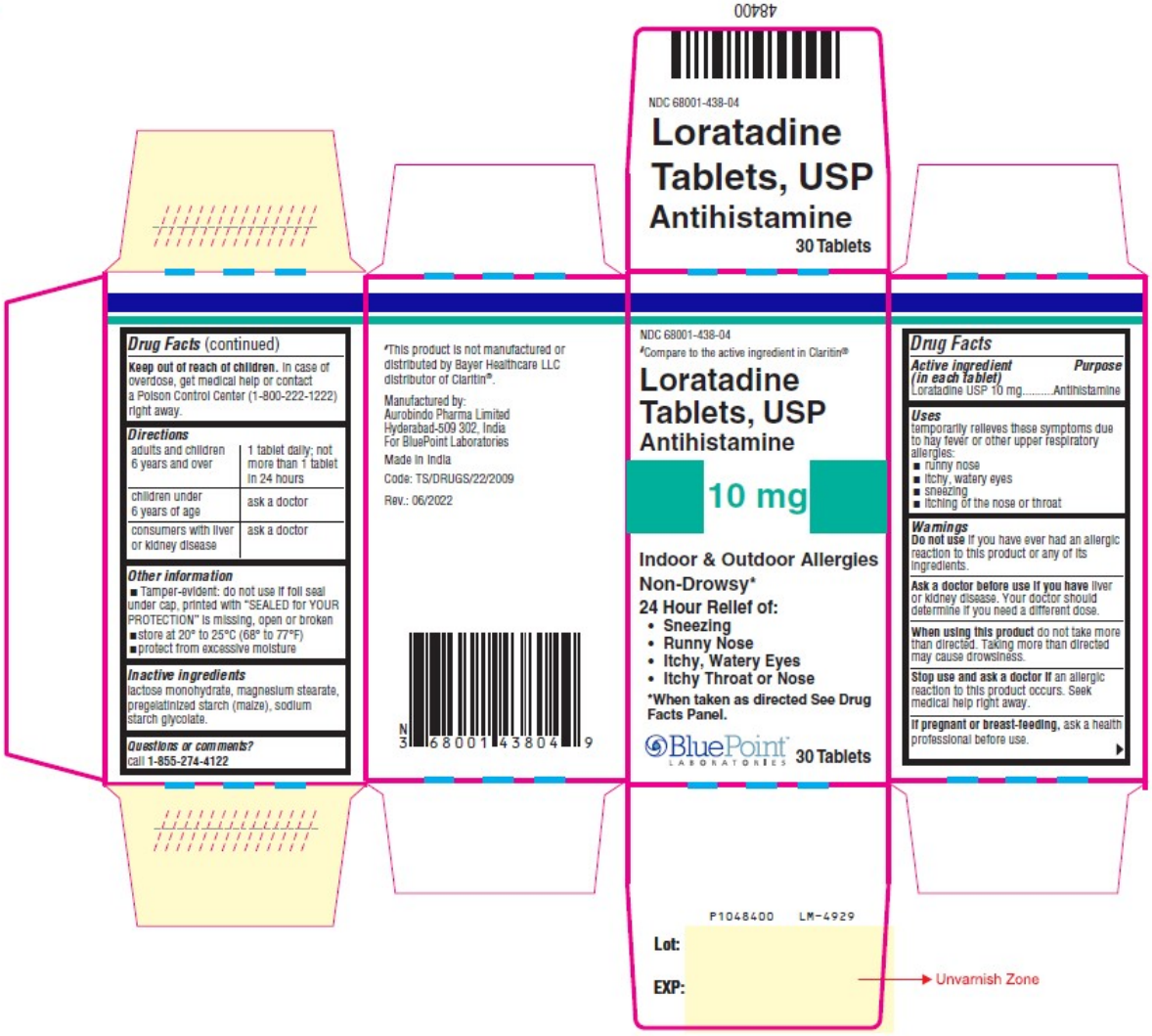
Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

*When taken as directed.

See Drug Facts Panel. 30 Tablets



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL- 10 mg Blister Carton (100 Tablets)

NDC 68001-438-96

#Compare to the active

ingredient in claritin®

Non-Drowsy*

Loratadine

Tablets USP 10mg

Antihisamine

Indoor and outdoor allergies

24 Hour

Relief of:

Sneezing

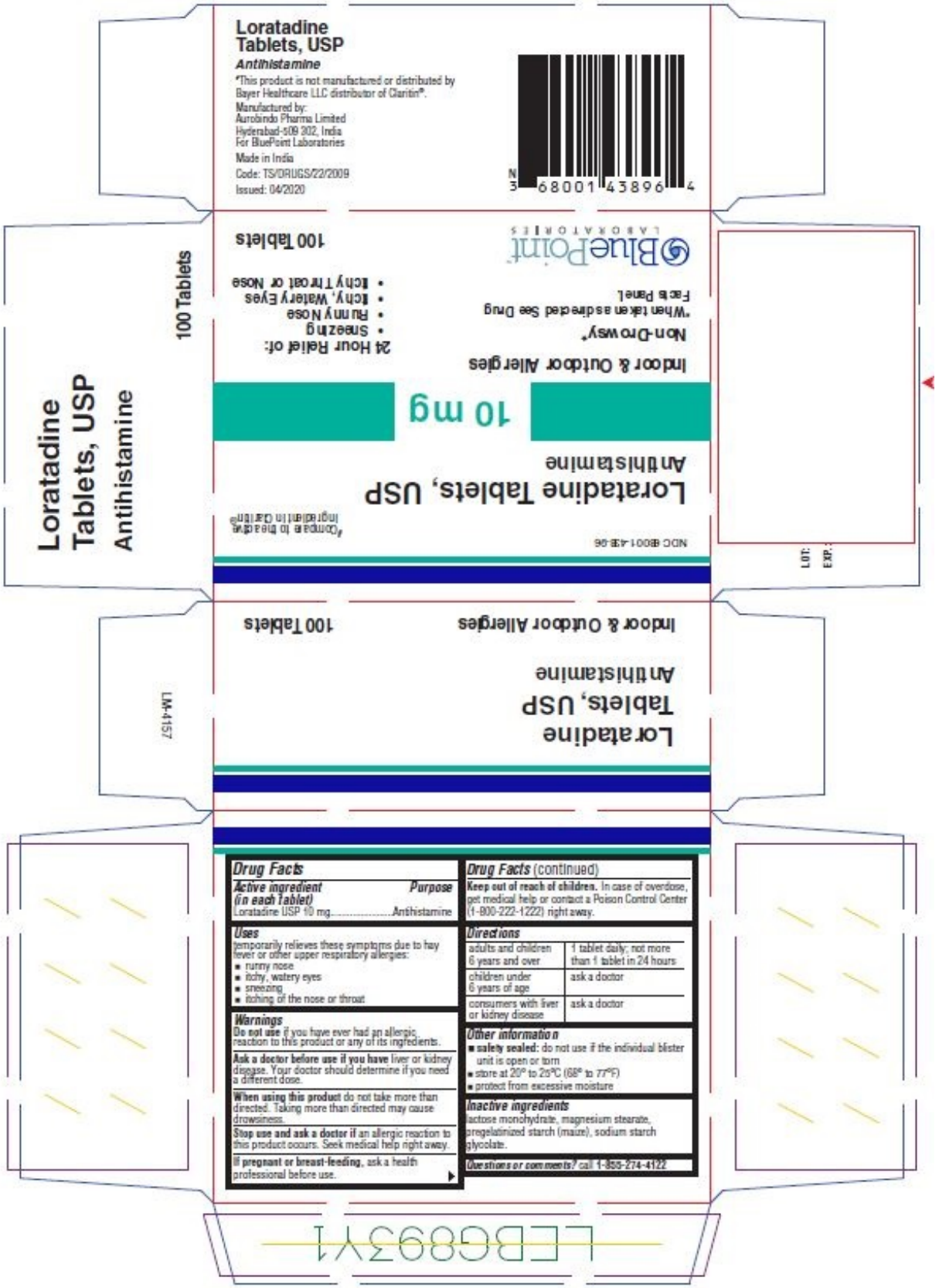
Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

***When taken as directed.**

See Drug Facts Panel. 100 Tablets



LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68001-438

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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
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:68001-438-00	1 in 1 CARTON	08/26/2020	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68001-438-96	10 in 1 CARTON	08/26/2020	
2	NDC:68001-438-16	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:68001-438-04	1 in 1 CARTON	08/26/2020	
3		30 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:68001-438-97	1 in 1 CARTON	08/26/2020	
4		300 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	08/26/2020	

Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	analysis(68001-438) , manufacture(68001-438)

Revised: 6/2022 BluePoint Laboratories