

LORATADINE- loratadine tablet
Advanced Rx LLC

Loratadine Tablets, 10 mg

Active ingredient(in each tablet)

Loratadine 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 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

- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

Inactive ingredients

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

Questions?

call **1-800-630-8895**

PRINCIPAL DISPLAY PANEL**NDC 80513-711-03**

Compare to the Active Ingredient in Claritin[®]*

Loratadine 10 mg

Allergy Relief

Non-Drowsy**

Antihistamine

24 Hour Relief of:

- Sneezing, runny nose
- Itchy, watery eyes
- Itchy throat or nose

Original Prescription Strength

****When Taken as Directed. See Drug Facts Panel.**

300 Tablets

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

***This product is not manufactured or distributed by the owner of the registered trademark Claritin[®]**

Distributed by:

ADVANCED RX LLC,

1942 NE 163rd St

North Miami Beach,

FL 33162 U.S.A.

5 52000 31508 3

COMPARE TO THE ACTIVE INGREDIENT IN CLARITIN®
LORATADINE 10 MG
ALLERGY RELIEF
 NON-DROWSY** ANTIHISTAMINE

24 HOUR RELIEF OF:

- ✔ Sneezing, runny nose
- ✔ Itchy, watery eyes
- ✔ Itchy throat or nose

100
 Tablets

ORIGINAL PRESCRIPTION STRENGTH
 **WHEN TAKEN AS DIRECTED. SEE DRUG FACTS PANEL.

INDOOR & OUTDOOR
 ALLERGY

NDC 80513-711-03

PUREGEN
 LABS

COMPARE TO THE ACTIVE INGREDIENT IN CLARITIN®

LORATADINE 10 MG
ALLERGY RELIEF

NON-DROWSY** ANTIHISTAMINE

24 HOUR RELIEF OF:

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INDOOR & OUTDOOR
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Drug Facts
Active ingredient
 (in each tablet) Loratadine 10 mg.....Antihistamine

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67043-300-106-0

PEEL FOR
 DIRECTIONS

LIFT HERE

Drug Facts (continued)

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HINGE

PEEL FOR
 DIRECTIONS

LIFT HERE

LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-711
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	G;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-711-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2024	
2	NDC:80513-711-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210722	01/01/2020	

Labeler - Advanced Rx LLC (042795108)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(80513-711)

Revised: 10/2024

Advanced Rx LLC