

LORATADINE- loratadine tablet
Aphena Pharma Solutions - Tennessee, LLC

Major Pharmaceuticals Allergy Drug Facts

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 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 right away. (1-800-222-1222)

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

- do not use if printed foil under cap is broken or missing
- store between 20° to 25° C (68° to 77° F)

Inactive ingredients

lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

Questions or comments?

1-800-719-9260

Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

Count	10 mg
90	71610-423-60

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:

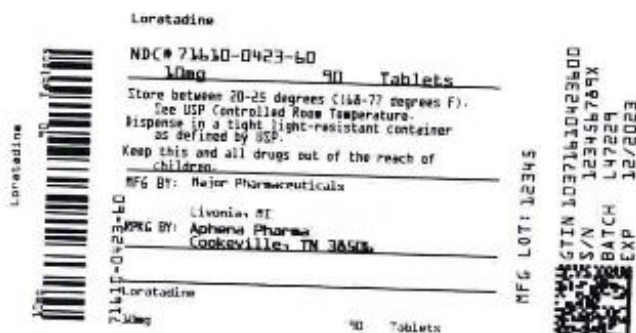


Cookeville, TN 38506

20200513JH

PRINCIPAL DISPLAY PANEL - 10 mg

NDC 71610-0423 - Loratadine 10 mg Tablets - Rx Only



LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:716 10-423(NDC:0904-6852)
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: EWQ57Q815X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	L612
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:716 10-423-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076301	12/06/2018	

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-423)

Revised: 5/2020

Aphena Pharma Solutions - Tennessee, LLC