LORATADINE- loratadine tablet Aphena Pharma Solutions - Tennessee, LLC

NorthStar RxLLC Loratadine Tablets 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?

1-800-206-7821

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:

Count10 mg9071610-553-60

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:

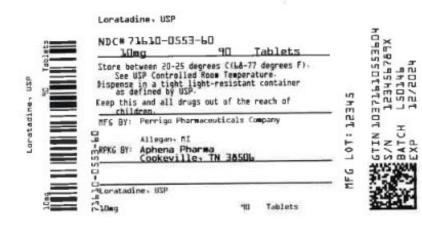


Cookeville, TN 38506

20210614JH

PRINCIPAL DISPLAY PANEL - 10 mg

NDC 71610-553 - Loratadine, USP 10 mg Tablets



LORATADINE						
oratadine tablet						
Product Information						
Product Type	HUMAN OTC DRUG	G Item Code (Source) NDC:71610		.0-553(NDC	D-553(NDC:16714-898)	
Route of Administration	ORAL					
Active Ingredient/Activ	e Moiety					
	redient Name		Basis of S	tronath	Strength	
LORATADINE (UNII: 7AJO3BO7Q				uengui	10 mg	
	N) (LORATADINE - UNII	.7AJUSBU7QN)	LORATADINE		TO HIG	
Inactive Ingredients						
Ingredient Name				St	Strength	
LACTOSE MONOHYDRATE (UN	III: EWQ57Q8I5X)					
MAGNESIUM STEARATE (UNII:	70097M6I30)					
POVIDONE (UNII: FZ989GH94E)						
Product Characteristic	-					
	-					
				8mm	no score	
Flavor	••••			L612		
Contains	IIIIk			2012		
Contains						
Packaging						
			kating Ctar			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:71610- 553-60	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2021	
Μ	larketing	Information		
M	l arketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
M	Marketing Category	Application Number or Monograph	-	-

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

Establishment							
Name	Address	ID/FEI	Business Operations				
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-553)				

Revised: 6/2021

Aphena Pharma Solutions - Tennessee, LLC