

**LORATADINE ANTIHISTAMINE- loratadine tablet**  
**Aphena Pharma Solutions - Tennessee, LLC**

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**Perrigo Loratadine Tablets, 10 mg 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 drug products listed below. This drug product has been received by Aphenia Pharma Solutions - Tennessee, LLC in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

### **10mg**

NDC 43353-259-60, Bottles of 90 Tablets  
NDC 43353-259-18, Bottles of 3000 Tablets  
NDC 43353-259-09, Bottles of 9000 Tablets

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

20240409AMH

# PRINCIPAL DISPLAY PANEL - 10 mg

NDC 43353-259 - Loratadine 10 mg Tablets



## LORATADINE ANTIHISTAMINE

loratadine tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43353-259(NDC:45802-650)
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (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:43353-259-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2016	
2	NDC:43353-259-18	3000 in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2022	

<b>3</b>	NDC:43353-259-09	9000 in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2022	
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**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076301	10/15/2008	

**Labeler** - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

**Establishment**

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	repack(43353-259)

Revised: 4/2024

Aphenia Pharma Solutions - Tennessee, LLC