

**MUCINEX- guaifenesin tablet, extended release**  
**Aphena Pharma Solutions - Tennessee, LLC**

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**Mucinex®**

***Drug Facts***

**Active ingredient (in each extended-release bi-layer tablet)**

Guaifenesin 600 mg

**Purpose**

Expectorant

**Uses**

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

**Do not use**

- for children under 12 years of age

**Ask a doctor before use if you have**

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

**Stop use and ask a doctor if**

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

**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.

**Directions**

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

**Other information**

- **Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing.**
- store between 20-25°C (68-77°F)

## Inactive ingredients

carbomer homopolymer type B; FD&C blue #1 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

## Questions?

**1-866-MUCINEX (1-866-682-4639)**

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser  
Parsippany, NJ 07054-0224

Made in England

## Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN 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:

Count	600 mg
60	67544-149-53
120	67544-149-70
180	67544-149-80

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:

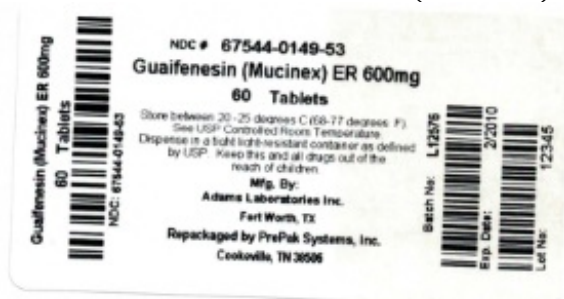


Cookeville, TN 38506

20171218DKJ

## PRINCIPAL DISPLAY PANEL - 600mg

NDC 67544-149 Guaifenesin (Mucinex) ER 600mg - Rx Only



# MUCINEX

guaifenesin tablet, extended release

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67544-149(NDC:63824-008)
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	600 mg

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

## Product Characteristics

Color	WHITE (blue and white)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	MucineX;600
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67544-149-53	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2012	
2	NDC:67544-149-70	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/22/2012	
3	NDC:67544-149-80	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/12/2012	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021282	07/03/2012	

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(67544-149)

Revised: 12/2017

Aphena Pharma Solutions - Tennessee, LLC