

MUCUS RELIEF - guaifenesin tablet, extended release
Aphena Pharma Solutions - Tennessee, LLC

MUCUS RELIEF
Guaifenesin Extended-Release Tablets 600 mg

ACTIVE INGREDIENT(in each extended-release tablet)

Guaifenesin 600 mg

PURPOSE

Expectorant

USE(S)

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

WARNING

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 (1-800-222-1222).

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 seal on the bottle printed "SEALED for YOU PROTECTION" is broken or missing.
- store between 20 to 25°C (68 to 77°F)

INACTIVE INGREDIENTS

carbomer homopolymer, hypromellose, microcrystalline cellulose, povidone

QUESTIONS?

1-800-616-2471

You may also report side effects to this phone number.

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
12	71610-499-12
60	71610-499-53

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

20201217JH

PRINCIPAL DISPLAY PANEL - 600 mg

NDC 71610-499 - Guaifenesin ER 600 mg Tablets

Guaifenesin ER

NDC# 71610-0499-53
600mg 60 Tablets

Store between 20-25 degrees (68-77 degrees 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.

MFG BY: Major Pharmaceuticals
Livonia, MI

RPKG BY: Aphena Pharma
Cookeville, TN 38506

MFG LOT: 12345

GTIN 10371610499537
S/N 123456789X
BATCH L48753
EXP 12/2024

Guaifenesin ER
600mg 60 Tablets

MUCUS RELIEF

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-499(NDC:0904-6986)
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, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	22mm

Flavor		Imprint Code	G233	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-499-12	12 in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2021	
2	NDC:71610-499-53	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA209215	09/23/2019		

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

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-499)

Revised: 5/2021

Aphenia Pharma Solutions - Tennessee, LLC