

MUCUS RELIEF- guaifenesin 200 mg tablet
Aphena Pharma Solutions - Tennessee, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Guaifenesin Caplets, 200 mg

Active ingredient (in each tablet)

Guaifenesin 200 mg

Purpose

Expectorant

Uses

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

Warnings

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 excessive phlegm (mucus)

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

IN CASE OF PREGNANCY OR BREAST FEEDING SECTION

ask a health professional before use

stop use and ask a doctor

if cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of serious illness

Directions:

- **adults and children 12 years of age and over:** take 1 to 2 tablets every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours.
- **children under 12 years:** do not use

OTHER INFORMATION

- store at 15°-30°C (59°-86°F)
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

colloidal silicon dioxide, FD&C RED#40(Al-lake), magnesium stearate, maltodextrin, microcrystalline

cellulose, stearic acid, sodium starch glycolate

Questions or Comments

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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	200 mg
3000	71610-098-18

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

20180718JH

PRINCIPAL DISPLAY PANEL - 200 mg

NDC 71610-098 - Guaifenesin 200 mg - Rx Only



MUCUS RELIEF

guaifenesin 200 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-098(NDC:54738-980)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	red	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	AP;151
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-098-18	3000 in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2016	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-098)

