

GUAIFENESIN 200MG- guaifenesin 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 200mg

GUAIFENESIN 200 MG TABLETS

Marlex Pharmaceuticals, Inc.

Drug Fact

Active ingredient (in each tablet)

Guaifenesin 200mg

Purpose

Expectorant

Guaifenesin 200 mg Tablets

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus and make coughs 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 too much phlegm (mucus)

Stop use and ask a doctor if

cough last more than 7 days, come back or is accompanied by fever, rash, or persistent headache. There could be signs of a serious illness.

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

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 take more than 6 doses in any 24-hour period.
- This product is not intended for use in children under 12 years of age
- Adults & children 12 years and over: 1 to 2 tablets every 4 hours
- Children under 12 years: do not use

Other Information:

- Store at 15°C-30°C (59°F-86°F)

Inactive Ingredients:

Colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, stearic acid

Manufactured for & Distributed by:

Marlex Pharmaceuticals, Inc.

New Castle, DE 19720

Rev: 02/19TCL

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	71610-434-18

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

20200619JH

PRINCIPAL DISPLAY PANEL - 200 mg

NDC 71610-434 - Guaifenesin 200 mg Tablets



GUAIFENESIN 200MG			
guaifenesin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:716 10 -434(NDC:10 135-68 1)
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POVIDONE (UNII: FZ989GH94E)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-434-18	3000 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/01/2019	

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

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-434)

Revised: 6/2020

Aphenia Pharma Solutions - Tennessee, LLC