## GUAIFENESIN 200MG- guaifenes in 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.

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## Guaifenes in 200 mg

#### **GUAIFENESIN 200 MG TABLETS**

Marlex Pharmaceuticals, Inc.

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**Drug Fact** 

## **Active ingredient (in each tablet)**

Guaifenesin 200mg

## **Purpose**

**Expectorant** 

## Guaifenes in 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 Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena 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

NDC # 71610-0434-18

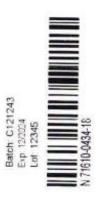
## Guaifenesin 200mg 3000 Tablets

Store between 20-25 degrees 0 (55-77 degrees F)
See USP Controlled Room Temperature
Dispense in a signt agric-resistant container as defined by USP
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Mfg. By: Marlex Pharmaceuticals Inc. New Castle, DE

Repackaged by Apnene Pharma Cookeville TN 38506

Guaifenesin 200mg 3000 Tablets



## **GUAIFENESIN 200MG**

guaifenesin tablet

#### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71610-434(NDC:10135-681)

**Route of Administration** 

ORAL

## **Active Ingredient/Active Moiety**

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

| Inactive Ingredients                            |          |  |  |
|---|----------|--|--|
| Ingredient Name                                 | Strength |  |  |
| SILICON DIO XIDE (UNII: ETJ7Z6XBU4)             |          |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)           |          |  |  |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D)                |          |  |  |
| CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U) |          |  |  |
| PO VIDO NE (UNII: FZ989 GH94E)                  |          |  |  |
| STEARIC ACID (UNII: 4ELV7Z65AP)                 |          |  |  |

| Product Characteristics |       |              |          |  |
|-------------------------|-------|--------------|----------|--|
| Color                   | WHITE | Score        | no score |  |
| Shape                   | ROUND | Size         | 8 mm     |  |
| Flavor                  |       | Imprint Code | G2       |  |
| Contains                |       |              |          |  |
|                         |       |              |          |  |

| Packaging             |   |                             |                           |  |
|-----------------------|---|-----------------------------|---------------------------|--|
| # Item Code           | Package Description                                 | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |  |
| 1 NDC:71610-434-18    | 3000 in 1 BOTTLE; Type 0: Not a Combination Product | 06/16/2020                  |                           |  |
|                       |   |                             |                           |  |
|                       |   |                             |                           |  |
| Marketing Information |   |                             |                           |  |
| Marketing Catego      | ory Application Number or Monograph Citation        | n Marketing Start Date      | Marketing End Date        |  |
| OTC MONOGRAPH FI      | NAL part341   | 03/01/2019                  |                           |  |
|                       | 1   |                             |                           |  |

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

| Establishment                            |         |           |                            |  |
|--|---------|-----------|----------------------------|--|
| Name                                     | Address | ID/FEI    | <b>Business Operations</b> |  |
| Aphena Pharma Solutions - Tennessee, LLC |         | 128385585 | REPACK(71610-434)          |  |

Revised: 6/2020 Aphena Pharma Solutions - Tennessee, LLC