

**GUAIFENESIN 400MG- guaifenesin tablet**  
**Marlex Pharmaceuticals Inc**

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**Guaifenesin 400mg**

**GUAIFENESIN400MG CAPLETS**

**MarlexPharmaceuticals, Inc.**

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**Drug Fact**

**Active ingredient (in each tablet)**

Guaifenesin 400mg

**Purpose**

Expectorant

**Guaifenesin 400 mg Caplets**

**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, comes back or is accompanied by fever, rash, or persistent headache. These 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:**

Maltodextrin, Povidone, Silicon Dioxide, Stearic acid.

**Manufactured for & Distributed by:**

Marlex Pharmaceuticals, Inc.

New Castle, DE 19720

**Rev. 03/24 AA**

**PRINCIPAL DISPLAY PANEL**

NDC 10135-0790-30

Guaifenesin

400 mg

30 CAPLETS

NDC 10135-0790-30

**MARLEX**  
PHARMACEUTICALS, INC.

**Guaifenesin**

400 mg

30 CAPLETS

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Guaifenesin 400 mg .....Expectorant

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Manufactured for/© attributed by:  
Marlex Pharmaceuticals, Inc.  
New Castle, DE 19720

Pat. 0324 AA



N 3 10135 79030 2

Read Here  
For More Drug Facts

Drug Facts (continued on back)

**Drug Facts (continued)**

**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 caplet every 4 hours
- children under 12 years: do not use

**Other information**

- store at 15°C - 30°C (59°F - 86°F)

**Inactive ingredients**  
Maltodextrin, Povidone, Silicon Dioxide, Stearic acid



**PRINCIPAL DISPLAY PANEL**

NDC 10135-0790-60  
Guaifenesin  
400 mg  
60 CAPLETS



**Drug Facts**  
**Active ingredient (in each caplet) Purpose**  
 Guaifenesin 400 mg .....Expectorant

**Uses** helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways 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 lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious illness.**

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

Manufactured for **Marlex Pharmaceuticals, Inc.**  
 New Castle, DE 19720  
 Rev. 03/24 AA



Peel Here For More Drug Facts  
 Drug Facts (continued on back)

**Drug Facts (continued)**  
 If pregnant or breastfeeding, 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 caplet every 4 hours  
 ■ children under 12 years: do not use

**Other information**  
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**Inactive ingredients**  
 Maltodextrin, Povidone, Silicon Dioxide, Stearic acid



# GUAIFENESIN 400MG

guaifenesin tablet

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10135-790 |
| <b>Route of Administration</b> | ORAL           |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN       | 400 mg   |

## Inactive Ingredients

| Ingredient Name                    | Strength |
|------------------------------------|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |          |
| MALTODEXTRIN (UNII: 7CVR7L4A2D)    |          |
| POVIDONE (UNII: FZ989GH94E)        |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)    |          |

## Product Characteristics

|              |                            |              |          |
|--------------|----------------------------|--------------|----------|
| <b>Color</b> | white (White to off white) | <b>Score</b> | no score |
|--------------|----------------------------|--------------|----------|

|                 |                  |                     |      |
|-----------------|------------------|---------------------|------|
| <b>Shape</b>    | CAPSULE (Caplet) | <b>Size</b>         | 14mm |
| <b>Flavor</b>   |                  | <b>Imprint Code</b> | C16  |
| <b>Contains</b> |                  |                     |      |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10135-790-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 03/01/2024           |                    |
| 2 | NDC:10135-790-60 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 03/01/2024           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012                                     | 03/01/2024           |                    |

**Labeler** - Marlex Pharmaceuticals Inc (782540215)

Revised: 3/2024

Marlex Pharmaceuticals Inc