

**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



**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

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**Ask a doctor before use if you have**

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
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**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/© attributed by:  
 Marlex Pharmaceuticals, Inc.  
 New Castle, DE 19720

Rec. 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 and distributed by:  
 Marlex Pharmaceuticals, Inc.  
 New Castle, DE 19720  
 Rev. 03/24 AA



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

**Drug Facts (continued)**  
 If pregnant or breastfeeding, ask a health professional before use.  
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**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  
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**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
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<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: 11/2025

Marlex Pharmaceuticals Inc