

**GUAIFENESIN 400MG- guaifenesin tablet**  
**Medline Industries**

*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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**987 Guaifenesin 400mg tablet**

***Active ingredient (in each immediate-release tablet)***

Guaifenesin 400 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

***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)

**When using this product**

- **do not exceed recommend dosage**
- do not use for more than 7 days

**Stop use and ask a doctor if**

- cough lasts for more than 7 days, recurs, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a healthcare 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***

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

***Other information***

- store at 25 degrees Celsius (77 degrees Fahrenheit) excursions permitted between 15 degrees to 30 degrees Celsius (fifty nine degrees to eighty six degrees Fahrenheit)
- keep in a dry place and do not expose to excessive heat

**Inactive ingredients**

colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid

**Questions or comments?**


Call toll free **1-800-MEDLINE (633-5463)**

Monday-Friday 9AM-5PM CST


**Package Label**

**1 inch  
Copy  
Free  
Area  
Needed  
for  
Hinge**

<b>Drug Facts</b> (continued)
<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ adults and children 12 years of age and older: take 1 tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours.</li> <li>■ Children under 12 years of age: do not use</li> </ul>
<p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)</li> <li>■ keep in a dry place and do not expose to excessive heat</li> </ul>
<p><b>Inactive ingredients</b></p> <p>colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid</p>
<p><b>Questions or comments?</b></p> <p>Call toll free <b>1-800-MEDLINE (633-5463)</b> Monday-Friday 9AM-5PM CST</p>



Immediate-release  
**Guaifenesin**  
400 mg  
Expectorant



**100**  
Tablets

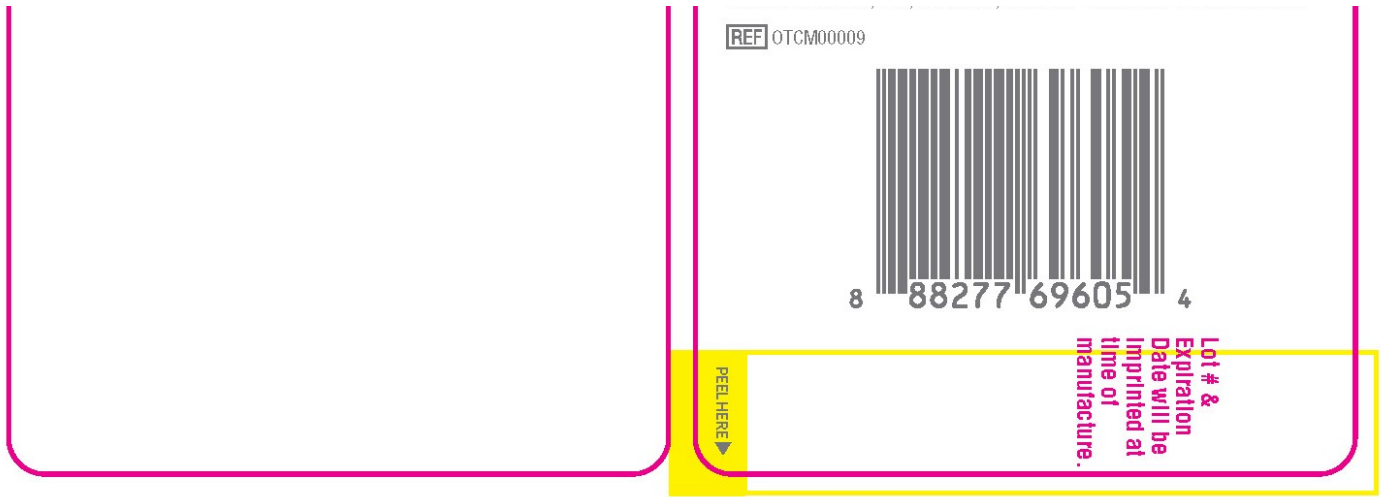
**400**  
mg

NDC 53329-987-62

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

<b>Drug Facts</b>	
<b>Active ingredient</b> (in each immediate-release tablet)	<b>Purpose</b>
Guaifenesin 400 mg .....	Expectorant
<p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive to rid the bronchial passageway of bothersome mucus</li> </ul>	
<p><b>Warnings</b></p> <p><b>Ask a doctor before use if you have</b> ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough accompanied by excessive phlegm (mucus)</p>	
<p><b>When using this product</b> ■ do not exceed recommend dosage</p> <ul style="list-style-type: none"> <li>■ do not use for more than 7 days</li> </ul>	
<p><b>Stop use and ask a doctor if</b> ■ cough lasts for more than 7 days, recurs, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.</p>	
<p><b>If pregnant or breast-feeding</b>, ask a healthcare professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. ▼</p>	

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## GUAIFENESIN 400MG

guaifenesin tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-987
Route of Administration	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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

### Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	TCL;272
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:53329-987-62	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2018	



### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/22/2018	

**Labeler** - Medline Industries (025460908)

### Establishment

Name	Address	ID/FEI	Business Operations
Time Cap Labs		037052099	manufacture(53329-987) , pack(53329-987)

### Establishment

Name	Address	ID/FEI	Business Operations
Medline Industries		079800021	repack(53329-987)