

**GUAIFENESIN - guaifenesin tablet**  
**Physicians Total Care, Inc.**

*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.*

-----

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

Guaifenesin 200 mg

**Purpose**

Expectorant

**Use(s)**

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 occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

**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 exceed 6 doses in 24 hours**
- take with a full glass of water

adults and children 12 years of age and over	1 to 2 tablets every 4 hours
children 6 to under 12 years of age	½ to 1 tablet every 4 hours
children under 6 years of age	consult a physician

**Other information**

- store at controlled room temperature 15°-30°C (59°-86°F)
- use by expiration date on package

**Inactive ingredients**

FD&C red #40 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silica gel, sodium starch glycolate, stearic acid

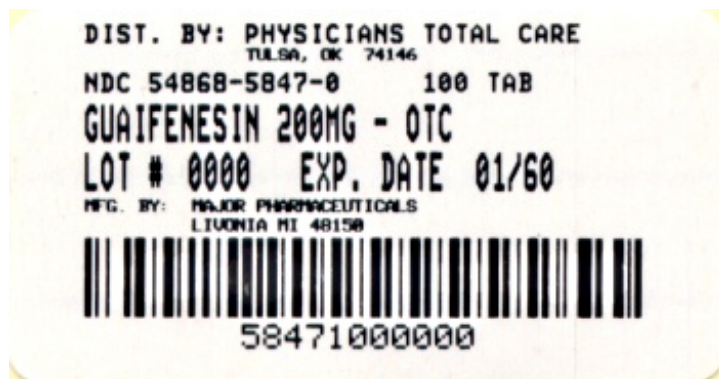
**Questions?**

**To Report Adverse Drug Event Call: (800) 616-2471**

**Principal Display Panel**

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

NDC 54868-5847-0



**GUAIFENESIN TABLETS**

Guaifenesin 200 mg

**Expectorant**

- Relieves Chest Congestion
- Thins and Loosens Mucus

100 Tablets **Immediate Release**

50844 REV0510A58812

**Distributed by MAJOR PHARMACEUTICALS**

31788 Enterprise Drive,

Livonia, MI 48150 USA

Re-Order No. 238163 M-17 Rev. 11/10

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

**Additional barcode labeling by:**

Physicians Total Care, Inc.

Tulsa, Oklahoma 74146

**GUAIFENESIN**

guaifenesin tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54868-5847(NDC:0904-5154)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

**Product Characteristics**

<b>Color</b>	PINK (dark)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	44;588
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54868-5847-0	1 in 1 CARTON		
1		100 in 1 BOTTLE, PLASTIC		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part341	01/07/2008	

**Labeler** - Physicians Total Care, Inc. (194123980)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Physicians Total Care, Inc.		194123980	relabel