

**GUAIFENESIN- guaifenesin tablet**  
**Contract Pharmacy Services-PA**

*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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**HIGHLIGHTS OF PRESCRIBING INFORMATION**

**Guaifenesin 200mg USP 251 "These highlights do not include all the information needed to use" "see full prescribing information for" "Initial U.S. Approval"**

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**DOSAGE AND ADMINISTRATION** -----

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 (3)

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**INDICATIONS AND USAGE** -----

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (6)

**Revised: 4/2018**

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**FULL PRESCRIBING INFORMATION: CONTENTS\***

\* Sections or subsections omitted from the full prescribing information are not listed.

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**FULL PRESCRIBING INFORMATION**

Major 44-588 Major Pharmaceuticals LNK International, Inc. LNK International, Inc. LNK International, Inc. LNK International, Inc. Guaifenesin Guaifenesin GUAIFENESIN GUAIFENESIN MAGNESIUM STEARATE MALTODEXTRIN CELLULOSE, MICROCRYSTALLINE POVIDONE STEARIC ACID FD&C RED NO. 40 SILICON DIOXIDE dark 44;588 Active ingredient (in each immediate-release tablet) Guaifenesin 200 mg Purpose 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 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 25°C (77°F); excursions permitted between 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 or comments? (800) 616-2471 Principal Display Panel NDC 0904-5154-60 MAJOR® GUAIFENESIN TABLETS Guaifenesin 200 mg Expectorant Relieves Chest Congestion Thins and Loosens Mucus 100 Tablets Immediate Release 50844 REV0812B58812 Distributed by MAJOR® PHARMACEUTICALS 31778 Enterprise Drive, Livonia, MI 48150 USA Re-Order No. 238163 M-17 Rev. 04/13 TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING Major 44-588 Major 44-588 □ REPACKAGED BY: COUPLER

ENTERPRISES INC. NDJA 4/19/18

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

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

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

Guaifenesin 200 mg

Expectorant

GUAIFENESIN  
200 MG TAB #30



309045154601

LOT: xxx  
PILL ID: 44 588  
EXP: 04/18/19  
MAJOR

Packaged By: Contract Pharmacy Services-PA  
125 Titus Ave, Suite #200, Warrington, PA 18976

Usual Adult Dosage: 1  
to 2 tablets every 4  
hours. Do not exceed  
6 doses in 24 hours.



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Store at controlled room temperature 15-30°C  
(59-86°F)

Each immediate-release tablet contains Guaifenesin 200  
mg

CPS NDC: 67046-251-30

# GUAIFENESIN

guaifenesin tablet

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-251(NDC:0904-5154)
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

## Product Characteristics

Color	pink	Score	2 pieces
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	44;588
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-251-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/15/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/15/2018	

**Labeler** - Contract Pharmacy Services-PA (945429777)

## Establishment

Name	Address	ID/FEI	Business Operations
Coupler Enterprises Inc.		945429777	repack(67046-251)