

GUAIFENESIN- guaifenesin tablet
Major Pharmaceuticals

Major 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

- cough accompanied by too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if

cough persists more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.

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 and over	1 to 2 tablets every 4 hours
children 6 to	1/4 to 1 tablet

under 12 years	72 to 1 tablet every 4 hours
children under 6 years	ask a doctor

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, silicon dioxide, sodium starch glycolate, stearic acid

Questions or comments?

1-800-426-9391

Principal Display Panel

MAJOR®

NDC 0904-5154-60

Immediate Release Guaifenesin

guaifenesin 200 mg

Expectorant

- Relieves Chest Congestion
- Thins and Loosens Mucus

Actual Size

100 Tablets

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

Distributed by: MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268 (800) 616-2471

www.major-rugby.com

Rev. 04/25 M-17 Re-order No. 238163

50844 REV0819E58812

MAJOR

NDC 0904-5154-60

**immediate release
guaifenesin**

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expectorant

- relieves chest congestion
- thins and loosens mucus

100 tablets



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PEEL HERE FOR MORE DRUG FACTS

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.						
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Questions or comments? 1-800-426-9391						

STOP PEELING

MAJOR 44-588

GUAIFENESIN

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	

MAGNESIUM STEARATE (UNII: 70097M6I30)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5154-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/05/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/05/2009	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0904-5154)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0904-5154)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(0904-5154)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0904-5154)

