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	½ to 1 tablet

under 12 years	½ to 1 tablet every 4 hours
children under 6 years	ask a doctor

Other information

- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- 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

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.majorpharmaceuticals.com
Rev. 03/24 M-17 Re-order No. 238163

50844 REV0819D58812

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)