# MUCUS ER- guaifenes in tablet, extended release Major Pharmaceuticals

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# Major Pharmaceuticals Mucus ER™ Drug Facts

# Active ingredient (in each extended-release tablet)

Guaifenesin 600 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

## Do not use

• for children under 12 years of age

# 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. (1-800-222-1222)

# **Directions**

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: one or two tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

# Other information

- do not use if printed seal under cap is broken or missing
- store between 20-25°C (68-77°F)

# **Inactive ingredients**

compressible sugar, copovidone, hydroxyethyl cellulose, silicon dioxide, zinc stearate

# Questions or comments?

1-800-719-9260

# Package/Label Principal Display Panel

Mucus ER<sup>TM</sup>

guaifenesin

extended-release tablets, 600 mg

**EXPECTORANT** 

12 HOUR

**Relieves Chest Congestion** 

Thins and Loosens Mucus

COMPARE TO active ingredient of MUCINEX®

Actual Size

# **MAJOR**°

# Mucus ER



**MAJOR**°

NDC 0904-6133-39

# Mucus ER

guaifenesin extended-release tablets, 600 mg

# **EXPECTORANT**



- ✓ Relieves Chest Congestion
- √ Thins and Loosens Mucus

COMPARE TO active ingredient of MUCINEX®\*

40 EXTENDED-RELEASE TABLETS



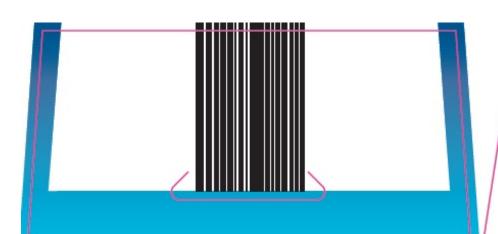




LOT NO.

EXP.

: 49858 5C C3



# MAJOR° MUCUS•ER°

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# **MAJOR**°

# Mucus

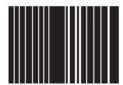
guaifenesin extended-release tablets, 600 mg

# **EXPECTORANT**

Distributed by MAJOR® PHARMACEUTICALS 31778 Enterprise Drive Livonia, MI 48150 USA M-05 REV. 05/12 Re-Order No. 100297

### **Gluten Free**

\*Major® Mucus•ER™ is not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex®.







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# **MUCUS ER**

guaifenesin tablet, extended release

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0904-6133

Route of Administration ORAL

# Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients		
Ingredient Name	Strength	
COPOVIDONE K25-31 (UNII: D9C330MD8B)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
ZINC STEARATE (UNII: H92E6QA4FV)		

Product Characteristics				
Color	WHITE ((off-white))	Score	no score	
Shape	ROUND	Size	12mm	
Flavor		Imprint Code	L498	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6133-95	1 in 1 CARTON		
1		20 in 1 BOTTLE		
2	NDC:0904-6133-39	1 in 1 CARTON		
2		40 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078912	03/20/2013		

# Labeler - Major Pharmaceuticals (191427277)

Revised: 3/2013 Major Pharmaceuticals