

**MUCUS RELIEF EXTENDED RELEASE- guaifenesin tablet**  
**Cardinal Health 107, LLC**

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**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 makes 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: 1 or 2 tablet every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

### **Other information**

- store between 20° to 25°C (68° to 77°F)

### **Inactive ingredients**

carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc

### **Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

### **Packaged and Distributed By:**

**MAJOR® PHARMACEUTICALS**

Indianapolis, IN 46268 USA

Refer to package label for Distributor's NDC Number

### **Distributed By:**

**Cardinal Health**

Dublin, OH 43017

L5769245-10124

L5769245-20124

### **Package Label**

Mucus Relief ER

Guaifenesin 600 mg

Expectorant

10 Extended-Release Tablets



X128

NDC 55154-4153-0

**MUCUS RELIEF ER  
GUAIFENESIN 600 MG  
EXPECTORANT**

**10 EXTENDED-RELEASE TABLETS**

Compare to the active ingredient in Mucinex<sup>®</sup>\*

**Drug Facts**

Active Ingredient (in each extended-release tablet)	Purpose
Guaifenesin 600 mg	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)

**WARNING:** This Unit Dose package is not child resistant and is

Intended for Institutional Use Only. Keep this and all drugs out of the reach of children.

Questions or comments?

Call 1-877-753-3935 Monday - Friday 9AM-5PM EST

\*This product is not manufactured or distributed by

Reckitt Benckiser LLC, distributor of Mucinex<sup>®</sup>.

Distributed by:

MAJOR<sup>®</sup> PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Distributed by Cardinal Health

Dublin, OH 43017

L5769245-10124

Lot: Exp:

Distributed by Cardinal Health  
Dublin, OH 43017

L5769245-20124

**Drug Facts (continued)**

**Warnings (continued)**

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 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. (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 timing of meals

■ adults and children 12 years of age and over:

1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours

■ children under 12 years of age: do not use

**TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS  
TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.**

**Other information**

■ store between 20° to 25° C (68° to 77° F)

**Inactive Ingredients** carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc

## MUCUS RELIEF EXTENDED RELEASE

guaifenesin tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55154-4153(NDC:0904-6718)
<b>Route of Administration</b>	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
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

<b>Product Characteristics</b>			
<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	AN036
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-4153-0	10 in 1 BAG	09/30/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207342	09/30/2018	

**Labeler** - Cardinal Health 107, LLC (118546603)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	REPACK(55154-4153)

Revised: 1/2024

Cardinal Health 107, LLC