

**MUCINEX- guaifenesin tablet, extended release**  
**American Health Packaging**

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**Mucinex**®

***Drug Facts***

**Active ingredient**  
**(in each extended-release bi-layer 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.

**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 tablets every 12 hours. Do not exceed 4 tablets in 24 hours.

- children under 12 years of age: do not use

**Other information**

- **FOR YOUR PROTECTION:** Do not use if blister is torn or broken.
- store between 20-25°C (68-77°F)

**Inactive ingredients**

carbomer homopolymer type B; FD&C blue #1 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

**Questions?**

**1-866-MUCINEX (1-866-682-4639)** for information about the drug product or to report side effects. For information about packaging, contact American Health Packaging at 1-800-707-4621.

\*The name MUCINEX<sup>®</sup> and associated trademarked items are used with permission by Reckitt Benckiser

The drug product contained in this package is from NDC # 63824-008 Reckitt Benckiser.

Packaged and Distributed by American Health Packaging, 2550 John Glenn Avenue, Suite A, Columbus, OH 43217

057201

5500408/0915

**Principal Display Panel - Carton - 600 mg**

NDC 68084-572-01

**Mucinex**<sup>®</sup>

600 mg guaifenesin  
extended-release bi-layer tablets

EXPECTORANT

12 HOUR

Unique Bi-Layer Tablet  
Immediate-Release Layer  
Extended-Release Layer

100 Tablets (10 x 10)

(01) 0 03 68084 572 01 2



**WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

**UNIT DOSE**

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Distributed by American Health Packaging,  
2550 John Glenn Avenue, Suite A, Columbus, OH 43217

057201  
5500406/0623

**EXPIRATION DATE & LOT NUMBER**

americanhealthpackaging.com



**Drug Facts**

Active ingredient (in each extended-release bi-layer tablet)	Purpose
Guaifenesin 600 mg	Expectorant
<i>Use:</i> Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.	
<b>Warnings</b> Do not use if for children under 12 years of age.	
<b>Ask a doctor before use if you have</b> <ul style="list-style-type: none"> <li>persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema</li> <li>cough accompanied by too much phlegm (mucus)</li> </ul>	
<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.</li> </ul>	
<b>If pregnant or breast-feeding, ask a health professional before use.</b> Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"> <li>do not crush, chew, or break tablet</li> <li>take with a full glass of water</li> <li>this product can be administered without regard for timing of meals</li> <li>adults and children 12 years of age and over, 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours</li> <li>children under 12 years of age, do not use.</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>FOR YOUR PROTECTION: Do not use if blister is torn or broken</li> <li>store between 20° to 25°C (68° to 77°F)</li> </ul>	
<b>Inactive ingredients:</b> carboxymethylcellulose, FD&C blue #1, aluminum lake, hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF	
<b>Questions?</b> Call 1-866-MUCINEX (1-866-682-4639) for information about the drug product or to report side effects. For information about the packaging, contact American Health Packaging at 1-866-707-4621.	

**NDC 68084-572-01**

**Mucinex**<sup>®</sup>

**600 mg guaifenesin  
extended-release bi-layer tablets**

**EXPECTORANT**

**100 Tablets (10 x 10)**

**Principal Display Panel - Blister - 600 mg**



Mucinex<sup>®</sup> (guaifenesin)  
 EXPECTORANT extended-  
 release bi-layer tablet **600 mg**

<b>MUCINEX</b>			
guaifenesin tablet, extended release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68084-572(NDC:63824-008)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	600 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
ALUMINUM OXIDE (UNII: LMI26O6933)			

<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01Z NK31)	

**Product Characteristics**

<b>Color</b>	white (blue and white)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	Mucinex;600
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68084-572-01	100 in 1 BOX, UNIT-DOSE	02/19/2016	
1	NDC:68084-572-11	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021282	02/19/2016	

**Labeler** - American Health Packaging (929561009)

## Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(68084-572)

Revised: 7/2024

American Health Packaging