MUCINEX- guaifenesin tablet, extended release Cardinal Health 107, LLC

Mucinex ®

Drug Facts

Active ingredient (in each extended-release bi-layer tablet)

Guaifenesin 600 mg

Purpose

Expectorant

12 Hour

Unique Bi-Layer Tablet

White Layer - Immediate Release Layer

Blue Layer - Extended-Release Layer

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.

This Unit Dose package is not child resistant and is Intended for Institutional Use Only. KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

If dispensed for outpatient use, a child-resistant container should be utilized.

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 $^{\otimes}$ 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

Americanhealthpackaging.com

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Distributed by:

Cardinal Health

Dublin, OH 43017

L5315882-10124

L5315882-20124

Principal Display Panel

Mucinex 600 mg

Guaifenesin

EXPECTORANT

10 Extended-Release Bi-Layer Tablets



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Drug Facts (continued)

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MUCINEX

guaifenesin tablet, extended release

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55154-4680(NDC:68084-572) **ORAL Route of Administration**

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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	white (blue and white)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	Mucinex;600
Contains			

F	Packaging				
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55154- 4680-0	10 in 1 BAG	01/01/2016		
1	L	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	01/01/2016	

Labeler - Cardinal Health 107, LLC (118546603)

Revised: 2/2024 Cardinal Health 107, LLC