MUCINEX- guaifenesin tablet, extended release American Health Packaging

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 $^{\mbox{\scriptsize I\!R}}$ 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[®]

600 mg guaifenesin extended-release bi-layer tablets

EXPECTORANT

100 Tablets (10 x 10)

Principal Display Panel - Blister - 600 mg



Mucinex[®] (guaifenesin) EXPECTORANT extendedrelease bi-layer tablet

600 mg

MUCINEX

guaifenesin tablet, extended release

	rmation								
Product Type		HUMAN OTC DRUG	ltem Code	e (Source) NDC:68084-57		4-572(NDC:	572(NDC:63824-008)		
Route of Admin	istration	ORAL							
A									
Active Ingredient/Active Moiety Ingredient Name Basis of Strength									
		Basis of St	trength	Strength					
GUAIFENESIN (UN	II: 495W7451VQ)) (GUAIFENES IN - UNII	:495W7451VQ)	Gl	JAIFENESIN		600 mg		
Inactive Ingredients									
		Ingredient	Name				Strength		
	OPOLYMER TY	PE B (ALLYL PENTAI		CROSSLINE	(UNII:				
HHT01ZNK31)									
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)									
ALUMINUM OXIDE (UNII: LMI2606933)									
UN/DDOMELLOCEO	HYPROMELLOSES (UNII: 3NXW29V3WO) MAGNESIUM STEARATE (UNII: 70097M6I30)								
MAGNESIUM STE	ARATE (UNII: 70	097M6I30)	1)						
MAGNESIUM STE	ARATE (UNII: 70)						
MAGNESIUM STE	ARATE (UNII: 70	097M6I30)))						
MAGNESIUM STE	ARATE (UNII: 70 Rocrystallin	097M6I30))						
MAGNESIUM STEA	ARATE (UNII: 70 Rocrystallin	097M6I30) IE (UNII: OP1R32D61U)) Scor	e		no score			
MAGNESIUM STEA CELLULOSE, MICI Product Char	ARATE (UNII: 70 ROCRYSTALLIN ACTERISTICS	097M6I30) IE (UNII: OP1R32D61U		e		no score 16mm			
MAGNESIUM STEA CELLULOSE, MICI Product Char Color	ARATE (UNII: 70 ROCRYSTALLIN acteristics white (blue a	097M6I30) IE (UNII: OP1R32D61U	Scor Size	e int Code			500		
MAGNESIUM STEA CELLULOSE, MICT Product Char Color Shape	ARATE (UNII: 70 ROCRYSTALLIN acteristics white (blue a	097M6I30) IE (UNII: OP1R32D61U	Scor Size			16mm	500		
MAGNESIUM STEA CELLULOSE, MICI Product Char Color Shape Flavor	ARATE (UNII: 70 ROCRYSTALLIN acteristics white (blue a	097M6I30) IE (UNII: OP1R32D61U	Scor Size			16mm	500		
MAGNESIUM STEA CELLULOSE, MICI Product Char Color Shape Flavor Contains	ARATE (UNII: 70 ROCRYSTALLIN acteristics white (blue a	097M6I30) IE (UNII: OP1R32D61U	Scor Size			16mm	500		
MAGNESIUM STEA CELLULOSE, MICI Product Char Color Shape Flavor	ARATE (UNII: 70 ROCRYSTALLIN acteristics white (blue a	097M6I30) IE (UNII: OP1R32D61U	Scor Size			16mm	500		
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Marketing I				
Marketing Category	Applicati	on Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021282		02/10/2016	

Labeler - American Health Packaging (929561009)

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

Revised: 10/2022

American Health Packaging