

MUCINEX - guaifenesin tablet, extended release
Dispensing Solutions, Inc.

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

- tamper evident: do not use if carton is open or if printed seal on blister is broken or missing
- 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)

You may also report side effects to this phone number.

Distributed by:

Reckitt Benckiser Inc.

Parsippany, NJ 07054-0224

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PRINCIPAL DISPLAY PANEL - 600mg Tablet

NDC 55045-3143-2

Mucinex®

600 mg guaifenesin extended-release bi-layer tablets

EXPECTORANT

**Chest
Congestion**

12
Hour

- **Thins And Loosens Mucus**
- **Relieves Chest Congestion**

20 EXTENDED-RELEASE BI-LAYER TABLETS

55045-3143-02 MUCINEX LABEL

BULK SOURCE DATA DIST. BY: RECKITT BENCKISER INC. PARSIPPANY, NJ 07054 PRODUCT ID: LIGHT BLUE / WHITE ROUND BI-LAYER TABLET DEBOSSED A / 600 BULK SOURCE NDC: 63824-0008-20 MFR. LOT: XXXXXX PEDIGREE #: 16161705 DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER 	 MUCINEX 600 mg 20 TABLETS NDC 55045-3143-02 PRODUCT # B2126 EACH EXTENDED-RELEASE BI-LAYER TABLET CONTAINS: GUAIFENESIN 600 mg Rev. Date: 09/09	WARNING: KEEP OUT OF CHILDREN'S REACH STORE BETWEEN 68° - 77°F SEE USP. B2126 NDC 55045-3143-02 MUCINEX 600 mg 20 TABLETS LOT # SAMPLE EXP: 00-00 MN 63824-0008-20 RX# 23241786 B2126 NDC 55045-3143-02 MUCINEX 600 mg 20 TABLETS LOT # SAMPLE EXP: 00-00 MN 63824-0008-20 RX# 23241786 B2126 NDC 55045-3143-02 MUCINEX 600 mg 20 TABLETS LOT # SAMPLE EXP: 00-00 MN 63824-0008-20 RX# 23241786 
TAKE _ ORALLY EVERY _ HOURS OR _ TIMES A DAY. DO NOT CRUSH, CHEW OR BREAK TABLET. TAKE WITH A FULL GLASS OF WATER.	LOT# SAMPLE EXP: 00-00 Rx # 23241786	Package Exclusively By: DISPENSING SOLUTIONS^{inc} Santa Ana, CA 92704

MUCINEX

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55045-3143(NDC:63824-008)
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
CARBOMER HOMO POLYMER TYPE B (UNII: HHT01ZNK31)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)	

Product Characteristics

Color	white (BLUE AND WHITE)	Score	no score
Shape	OVAL	Size	16 mm
Flavor		Imprint Code	Mucinex;600
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55045-3143-2	20 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021282	05/12/2010	

Labeler - Dispensing Solutions, Inc. (066070785)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel, repack

Revised: 6/2011

Dispensing Solutions, Inc.