MUCINEX- guaifenes in tablet, extended release Proficient Rx LP

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.

Dist. by: Reckitt Benckiser Parsippany, NJ 07054-0224

Relabeled by: Proficient Rx LP Thousand Oaks, CA 91320

Made in England

PRINCIPAL DISPLAY PANEL - 40 Tablet Carton

NDC 63187-954-20

Mucinex® 600 mg guaifenesin extended-release bi-layer tablets EXPECTORANT

12 HOUR

- Relieves Chest Congestion
- Thins and Loosens Mucus
- Immediate and Extended Release

20 EXTENDED-RELEASE BI-LAYER TABLETS





NDC 63187-954-20

Lot #:00000 Exp. 00/00/00 SN# MASTER

Mucinex 600mg #20 ER Tablets Lot #00000 NDC 63187-954-20

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Mucinex 600mg #20 ER Tablets Lot #00000 NDC 63187-954-20

SN# MASTER Exp:00/00/00

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320

Mucinex 600mg

#20 ER Tablets

Each extended-release bi-layer tablet contains: Guaifenesin 600 mg Expectorant

White (blue and white) oval shaped unscored tablet with imprint code "Mucinex 600"

Product ID: RM095420

Dist. By: Reckitt Benckiser Parsippany, NJ 07054-0224 Made in England

Store between 20-25°C (68-77°F)

Keep medication out of the reach of children

MUCINEX

guaifenesin tablet, extended release

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:63187-954(NDC:63824-008)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
I	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)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

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:63187-954-20	20 in 1 CARTON; Type 0: Not a Combination Product	08/01/2019	
2 NDC:63187-954-40 40 in 1 CARTON; Type 0: Not a Combination Product 01/01/2018				
Marketing Information				
N	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
N	DA	NDA021282	07/03/2012	

Labeler - Proficient Rx LP (079196022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Proficient Rx LP		079196022	RELABEL(63187-954)	

Revised: 1/2021 Proficient Rx LP