MUCINEX- guaifenes in tablet, extended release Atlantic Biologicals Corps

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.

ask a health professional before use. If pregnant or breast-feeding,

In case of overdose, get medical help or contact a Poison Control Center right away. **Keep out of reach of children.**

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

MUCINEX (GUAIFENESIN) TABLET, EXTENDED RELEASE

17856-0008-02 MUCINEX (GUAIFENESIN) 600MG EXTENDED-RELEASE BI-LAYER TABLETS

04/40

See package insert for indications and dosage schedule

Store between 20°-25°C (68°-77°F) KEEP OUT OF THE REACH OF CHILDREN

17856-0008-02

Dosage: 600 MG ER-TAB

MUCINEX

Qty: 100 TAB

GTIN: 00117856000822

S/N: 34726300000002

OTC

Exp: 01/31/20

Lot: 347263

17856000802

Packaged by: Unit Dose Solutions Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp, Miami FI 33179

Call to Reorder: 800.509.7592

MUCINEX

guaifenesin tablet, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0008(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 HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			

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

	Pa	ckaging			
ı	# Item Code Package Description		Package Description	Marketing Start Date	Marketing End Date
ı	1 N	DC:17856-0008-2	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	0 1/11/20 21	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021282	07/03/2012	

Labeler - Atlantic Biologicals Corps (047437707)

Establishment			
Name	Address	ID/FEI	Business Operations
Atlantic Biologicals Corps		047437707	REPACK(17856-0008), relabel(17856-0008)

Revised: 1/2021 Atlantic Biologicals Corps