MUCINEX- guaifenesin tablet, extended release ATLANTIC BIOLOGICAS CORP.

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)
Extended-Release
Bi-Layer Tablets

DELIVERS 1TAB/600mg



See package insert for indications and dosage schedule

Helps loosen phlegm (mucus) and thin bronchital secretions to rid the bronchital passageways of bothersome mucus and makes coughs more productive. DO NOT Break, Chew, or Crush tablet. Store at 20°-25°C (68°-77°F) **Keep this and all Medications out of the reach of children**



17856-0008-02 Dosage 1TAB/600mg

Mucinex (Guaifenesin)
Extended-Release Tablets

Qty: 100

GTIN: 00117856000822

S/N: XXXXXXXXXXXX

Exp: 03/07/24

Lot: XXXXXXXXXXX

OTC

Packaged by:

Distributed by: Atlantic Biologicals Corp. Miami, FL 33179

Rev.08/21

Call to Reorder:

MUCINEX

quaifenesin 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			
Basis of Strength	Strength		
Guaifenesin	600 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			

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

ı	Packaging			
# Item Code Package Description		Package Description	Marketing Start Date	Marketing End Date
	1 NDC:17856- 0008-2	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/05/2024	

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

Labeler - ATLANTIC BIOLOGICAS CORP. (047437707)

Establishment					
Name	Address	ID/FEI	Business Operations		
UNIT DOSE SOLUTIONS		360804194	REPACK(17856-0008)		

Revised: 6/2024 ATLANTIC BIOLOGICAS CORP.