MUCINEX DM- guaifenesin and dextromethorphan hydrobromide tablet, extended release
ATLANTIC BIOLOGICALS CORP.

Mucinex DM

600 mg guaifenesin & 30 mg dextromethorphan HBr extended-release bi-layer tablets

EXPECTORANT & COUGH SUPPRESSANT

Drug Facts

Active ingredients (in each extended-release bi-layer tablet)	***Purposes***
Dextromethorphan HBr 30 mg	Cough suppressant
Guaifenesin 600 mg	Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

Warnings

Do not use

- for children under 12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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)

When using this product

- do not use more than directed

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 timing of meals
- adults and children 12 years and older: 1 or 2 tablets every 12 hours; not more than 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; D&C yellow #10 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:
Atlantic Biologicals
Miami, Fl 33179

PRINCIPAL DISPLAY PANEL - 20 Tablet Carton

NDC 17856-0056-1

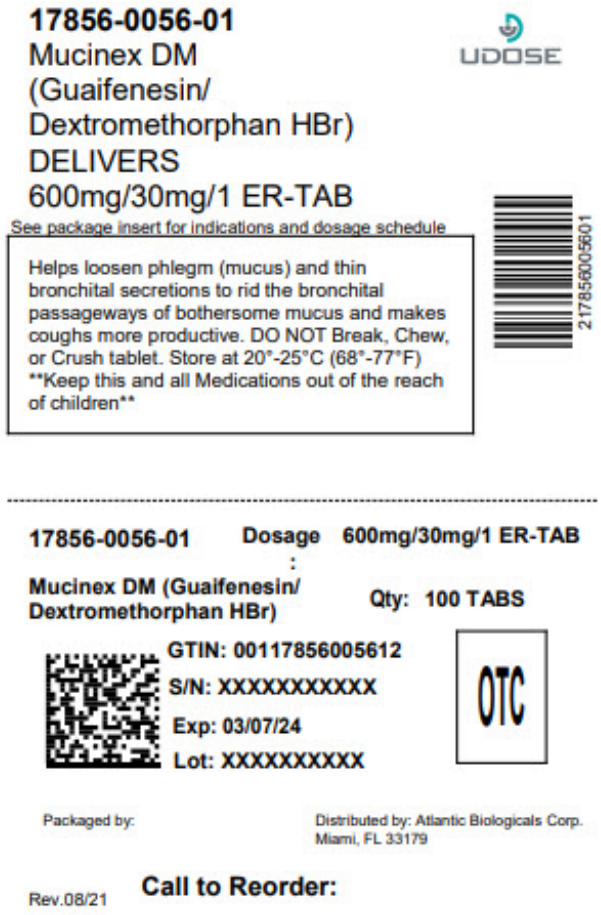
Mucinex DM
600 mg guaifenesin & 30 mg dextromethorphan HBr
extended-release bi-layer tablets

EXPECTORANT & COUGH SUPPRESSANT

12
HOUR

✓
Controls Cough
✓
Thins and Loosens Mucus
✓
Immediate and Extended Release

20
EXTENDED-RELEASE
BI-LAYER TABLETS



MUCINEX DM

guaifenesin and dextromethorphan hydrobromide tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-0056(NDC:63824-056)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	600 mg
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	30 mg

Inactive Ingredients

Ingredient Name	Strength
Carbomer Homopolymer Type B (Allyl Pentaerythritol Crosslinked) (UNII: HHT01ZNK31)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
aluminum oxide (UNII: LMI26O6933)	
hypromelloses (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
cellulose, microcrystalline (UNII: OP1R32D61U)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0056-1	1 in 1 PACKAGE; Type 0: Not a Combination Product	05/08/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021620	06/26/2012	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0056)

Revised: 5/2024 ATLANTIC BIOLOGICALS CORP.