MUCINEX DM- guaifenesin and dextromethorphan hydrobromide tablet, extended release Select Consumer Group

Mucinex® DM

Drug Facts

Active ingredients (in each extended-release tablet)
Dextromethorphan HBr 30 mg
Guaifenesin 600 mg

Active ingredients (in each extended-release 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 extended-release 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 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

store at 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B; D&C yellow no. 10 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Questions?

1-866-MUCINEX (1-866-682-4639)

Dist. by: RB Health (US) Parsippany, NJ 07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - 20 Tablet Blister Pack Carton

NDC 63824-056-32

Mucinex ® DM

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

EXPECTORANT & COUGH SUPPRESSANT

12

HOUR ®

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

20

EXTENDED-RELEASE TABLETS



MUCINEX DM

guaifenesin and dextromethorphan hydrobromide tablet, extended release

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:85237-1650(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: LMI2606933)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (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:85237- 1650-1	2 in 1 POUCH; Type 0: Not a Combination Product	06/26/2012	

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

Labeler - Select Consumer Group (119185084)

Registrant - Select Consumer Group (119185084)

Establishment				
Name	Address	ID/FEI	Business Operations	
Select Consumer Group		119185084	repack(85237-1650)	

Revised: 8/2025 Select Consumer Group