# MUCINEX DM- guaifenesin and dextromethorphan hydrobromide tablet, extended release RB Health (US) LLC

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#### 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: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	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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			

<b>‡</b>	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824- 056-89	4 in 1 CARTON	03/30/2018	
1		17 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824- 056-36	1 in 1 CARTON	06/26/2012	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63824- 056-32	1 in 1 CARTON	06/26/2012	
3		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:63824- 056-34	2 in 1 CARTON	06/26/2012	
4		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:63824- 056-69	3 in 1 CARTON	06/26/2012	
5		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:63824- 056-74	24 in 1 CARTON	06/26/2012	
6	NDC:63824- 056-73	2 in 1 POUCH; Type 0: Not a Combination Product		
7	NDC:63824- 056-72	2 in 1 POUCH; Type 0: Not a Combination Product	06/26/2012	
8	NDC:63824- 056-11	2 in 1 CARTON	06/26/2012	06/15/2022
8		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
9	NDC:63824- 056-01	5 in 1 CARTON	06/26/2012	
9		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
LO	NDC:63824- 056-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2021	
L <b>1</b>	NDC:63824- 056-80	2 in 1 CARTON	05/01/2024	
11		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		

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

## Labeler - RB Health (US) LLC (081049410)

Revised: 4/2025 RB Health (US) LLC