

**MUCINEX DM - guaifenesin and dextromethorphan hydrobromide tablet, extended release**  
**Physicians Total Care, Inc.**

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**Mucinex®DM**

***Drug Facts***

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<b><i>Active ingredients (in each extended-release bi-layer tablet)</i></b>	<b><i>Purpose</i></b>
Dextromethorphan HBr 60 mg	Cough suppressant
Guaifenesin 1200 mg	Expectorant

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**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 tablet every 12 hours; not more than 2 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 at 20-25°C (68-77°F)

**Inactive ingredients**

carbomer 934P, NF; D&C yellow #10 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Distributed by:

Reckitt Benckiser Inc.

Parsippany, NJ 07054-0224

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Relabeling of "Additional Barcode" by:

Physicians Total Care, Inc.

Tulsa, OK 74146

**PRINCIPAL DISPLAY PANEL - 1200 mg Carton**

**MAXIMUM STRENGTH**

NDC 54868-6106-0

**Mucinex®DM**

**1200 mg guaifenesin & 60 mg dextromethorphan HBr  
extended-release bi-layer tablets**

**EXPECTORANT & COUGH SUPPRESSANT**

12 HOUR

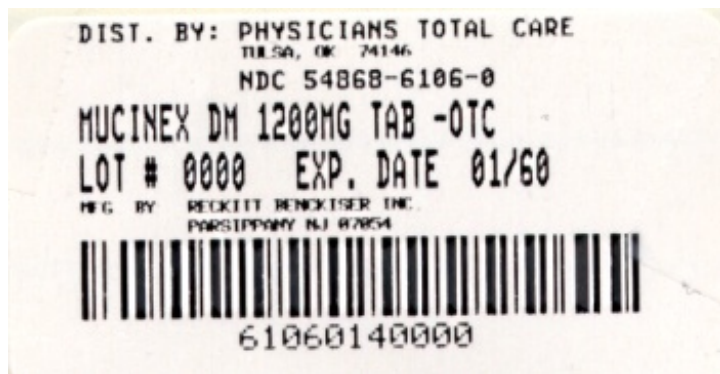
NEW LOOK-

SAME RELIEF

**Thins And Loosens Mucus**

**Controls Cough**

**14 EXTENDED-RELEASE BI-LAYER TABLETS**



## MUCINEX DM

guaifenesin and dextromethorphan hydrobromide tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54868-6106(NDC:63824-072)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	white (yellow and white)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	Mucinex;1200
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-6106-0	2 in 1 CARTON		
1		7 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021620	04/19/2010	

**Labeler** - Physicians Total Care, Inc. (194123980)

## Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 12/2009

Physicians Total Care, Inc.