

**MUCINEX D - guaifenesin and pseudoephedrine hydrochloride tablet, extended release**  
**Physicians Total Care, Inc.**

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**Mucinex®D**

***Drug Facts***

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<b><i>Active ingredients (in each extended-release bi-layer tablet)</i></b>	<b><i>Purpose</i></b>
Guaifenesin 600 mg	Expectorant
Pseudoephedrine HCl 60 mg	Nasal Decongestant

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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 nasal congestion due to:
  - common cold
  - hay fever
  - upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

**Warnings**

**Do not use** 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**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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**

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a 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: 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 at 20-25°C (68-77°F)

**Inactive ingredients**

carbomer 934P, NF; FD&C yellow #6 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 - 600 mg Carton**

NDC 54868-5849-0

**Mucinex®D**

**600 mg guaifenesin & 60 mg pseudoephedrine HCl  
extended-release bi-layer tablets**

**EXPECTORANT & NASAL DECONGESTANT**

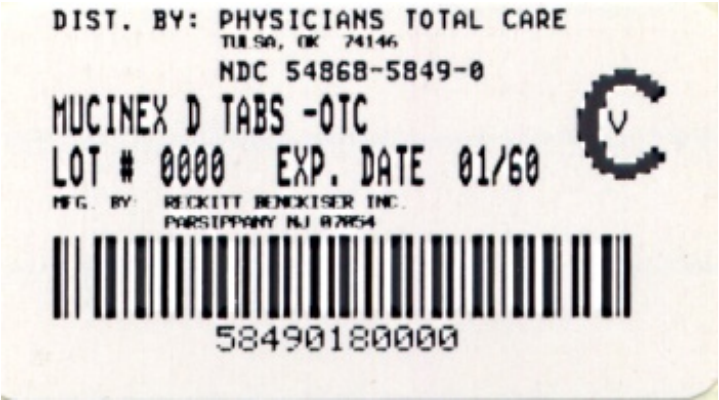
12 HOUR

NEW LOOK-  
SAME RELIEF

**Thins And Loosens Mucus**

**Clears Nasal/Sinus Congestion**

**18 EXTENDED-RELEASE BI-LAYER TABLETS**



**MUCINEX D**

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

Product Information					
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:54868-5849(NDC:63824-057)
Route of Administration		ORAL			
Active Ingredient/Active Moiety					
Ingredient Name				Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)				GUAIFENESIN	600 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)				PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg
Inactive Ingredients					
Ingredient Name					Strength
CARBOMER 934 (UNII: Z135WT9208)					
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)					
HYPROMELLOSE (UNII: 3NXW29V3WO)					
MAGNESIUM STEARATE (UNII: 70097M6I30)					
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)					
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)					
Product Characteristics					
Color	orange, 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:54868-5849-0	2 in 1 CARTON			
1		9 in 1 BLISTER PACK			

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021585	01/07/2008	

**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.