

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

Mucinex®D

Drug Facts

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

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

DIST. BY: PHYSICIANS TOTAL CARE
TULSA, OK 74146

NDC 54868-5849-0

MUCINEX D TABS -OTC

LOT # 0000 EXP. DATE 01/60

MFG. BY: BECKETT BENCKISER INC.
PARLISPPANY, NJ 07654



58490180000

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:7CUC9DD19F)	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.