

MUCINEX D- guaifenesin and pseudoephedrine hydrochloride tablet, extended release
RB Health (US) LLC

Mucinex®D

Drug Facts

<i>Active ingredients (in each extended-release bi-layer tablet)</i>	<i>Purposes</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 homopolymer type B; FD&C yellow #6 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Questions ?

1-866-MUCINEX (1-866-682-4639) You may also report side effects to this phone number.

Dist. by: RB Health (US)

Parsippany, NJ 07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - 18 Tablet Carton

NDC 63824-057-18

Mucinex®D

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

**EXPECTORANT
& NASAL DECONGESTANT**

**12
HOUR**

- **Clears Nasal/Sinus Congestion**
- **Thins and Loosens Mucus**
- **Immediate and Extended Release**

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

Glue Line

NDC 63824-057-18

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18 EXTENDED-RELEASE
BI-LAYER TABLETS

Choose from
the MUCINEX[®]
line of products
to treat your
symptoms

MUCINEX[®] Relieves Chest Congestion • Thins and Loosens Mucus for 12 hours
MUCINEX[®] DM Controls Cough • Thins and Loosens Mucus for 12 hours
MUCINEX[®] D Clears Nasal/Sinus Congestion • Thins and Loosens Mucus for 12 hours

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Mucinex[®]D
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EXPECTORANT
& NASAL DECONGESTANT



3 63824 05718 2

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Drug Facts (continued)
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Uses
Pseudoephedrine HCl 60 mg..... Nasal Decongestant
Guaifenesin 600 mg..... Expectorant

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bi-layer tablet)

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Dist. by: RB Health (US)
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HEALTH • HYGIENE • HOME

Patents: www.rb.com/patents

Please visit our website
www.mucinex.com

Contains FD&C Yellow Dye #6

Tablet shown actual size

Extended-Release Layer

Immediate-Release Layer

Unique Bi-Layer Tablet

Tablet shown actual size

Extended-Release Layer

Immediate-Release Layer

Unique Bi-Layer Tablet

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Tablet shown actual size

Mucinex[®]D
600 mg guaifenesin & 60 mg pseudoephedrine HCl
extended-release bi-layer tablets

EXPECTORANT

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: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 homopolymer type B (allyl pentaerythritol crosslinked) (UNII: HHT01ZNK31)	
FD&C yellow NO. 6 (UNII: H77VEI93A8)	
aluminum oxide (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

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:63824-057-18	1 in 1 CARTON	06/26/2012	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824-057-36	4 in 1 CARTON	06/26/2012	
2		9 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	NDA021585	06/26/2012	

