

**MUCINEX D - guaifenesin and pseudoephedrine hydrochloride tablet, extended release**  
**Dispensing Solutions 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

### How Supplied

Mucinex®D is supplied by **Dispensing Solutions Inc.** as follows:

NDC	Strength	Quantity/Form	Color	Source NDC
68258-3035-1	600 mg / 60 mg	18 Tablets	WHITE	63824-057-18

This product was:

#### Distributed by:

Reckitt Benckiser Inc.  
Parsippany, NJ 07054-0224

And Relabeled By:

#### Dispensing Solutions Inc.

3000 West Warner Ave  
Santa Ana, CA 92704  
United States

### PRINCIPAL DISPLAY PANEL - 600 mg Carton

NDC 68258-3035-1

#### 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**

BULK SOURCE DATA  
**DIST. BY: RECKITT BENCKISER INC.**  
**PARSIPPANY, NJ 07054**

**PRODUCT ID:**  
 WHITE / BLUE / GRAY / ORANGE /  
 DARK ORANGE / YELLOW / BLACK  
 BOX PRINTED NDC 63824-057-18

**BULK SOURCE NDC: 63824-0057-18**  
**MFR LOT: XXXXXX**

**PEDIGREE #: XXXXXXXX**  
**DISPENSE IN THIS**  
**TIGHT/LIGHT RESISTANT CONTAINER**





**MUCINEX D 600 mg/60 mg**  
**18 EXTENDED-RELEASE TABLETS**

**NDC 68258-3035-01**  
**PRODUCT # 8M0518**

EACH EXTENDED-RELEASE  
 BI-LAYER TABLET CONTAINS:  
 GUAIFENESIN 600 mg (EXPECTORANT)  
 PSEUDOEPHEDRINE HCl 60 mg (NASAL DECONGESTANT)  
 ALSO CONTAINS FD&C YELLOW No. 6

**LOT# SAMPLE EXP: 00-00 Rx # 20692847**

**WARNING: KEEP OUT OF CHILDREN'S REACH  
 STORE AT 68°- 77° F. SEE USP.**

**8M0518 NDC 68258-3035-01**  
**MUCINEX D 600 mg/60 mg**  
**18 EXTENDED-RELEASE TABLETS**  
**LOT # SAMPLE EXP: 00-00**  
**MN 63824-0057-18 RX# 20692847**

**8M0518 NDC 68258-3035-01**  
**MUCINEX D 600 mg/60 mg**  
**18 EXTENDED-RELEASE TABLETS**  
**LOT # SAMPLE EXP: 00-00**  
**MN 63824-0057-18 RX# 20692847**

**8M0518 NDC 68258-3035-01**  
**MUCINEX D 600 mg/60 mg**  
**18 EXTENDED-RELEASE TABLETS**  
**LOT # SAMPLE EXP: 00-00**  
**MN 63824-0057-18 RX# 20692847**



Packaged Exclusively By:  
**DISPENSING SOLUTIONS**   
 Santa Ana, CA 92704

**Rev. Date: 11/09**

**TAKE \_\_\_\_\_ ORALLY EVERY \_\_\_\_\_  
 HOURS OR \_\_\_\_\_ TIMES A DAY.  
 DO NOT CRUSH, CHEW OR  
 BREAK TABLET. TAKE WITH  
 A FULL GLASS OF WATER.**

**MUCINEX D**

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68258-3035(NDC:63824-057-18)
<b>Route of Administration</b>	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

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	Mucinex;600
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68258-3035-1	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	02/08/2008	

**Labeler** - Dispensing Solutions Inc. (066070785)

## Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions Inc.		066070785	repack, relabel

Revised: 3/2010

Dispensing Solutions Inc.