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

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Mucinex® D Maximum Strength

**Drug Facts** 

Active ingredients (in each extended- release bi-layer tablet)	Purposes
Guaifenesin 1200 mg	Expectorant
Pseudoephedrine HCl 120 mg	Nasal
Pseudoephedrine HCi 120 mg	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: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

#### Other information

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 - 24 Tablet Blister Pack Carton

MAXIMUM STRENGTH

NDC 63824-041-24

Mucinex®D 1200 mg guaifenesin & 120 mg pseudoephedrine HCl extended-release bi-layer tablets

EXPECTORANT & NASAL DECONGESTANT

## 12 $\mathsf{HOUR}_{\circledR}$

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

24 **EXTENDED-RELEASE BI-LAYER TABLETS** 

lamper evident: Do not use if carton is open or if printed seal on blister is broken or misserin.

ves Chest Congestion - Trains and Loosens Mucus for 12 hours
Controls Cough - Thins and Loosens Mucus for 12 hours

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

Relieves Chest Congestion . Thins and Loosens Mucus for 12 hours

#### MAXIMUM STRENGTH

# Mucinex

1200 mg guaifenesin & 120 mg pseudoephedrine HCI extended-release bi-layer tablets

#### **EXPECTORANT** & NASAL DECONGESTANT

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✓ Thins and Loosens Mucus ✓ Immediate and Extended Release



**EXTENDED-RELEASE** 

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(in each extended-release

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bi-layer tablet)

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MAXIMUM STRENGTH

EXPECTORANT NASAL DECONGESTANT

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Patents: www.rb.com/patents ммм.тисіпех.сот Please visit our website

Contains FD&C Yellow Dye #6

Tablet shown actual size

Extended-Release Layer

Im med iate-Relea se Layer

Unique Bi-Layer Tablet

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**Drug Facts** (continued)

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EXPECTORANT & NASAL DECONGESTANT





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## MUCINEX D MAXIMUM STRENGTH

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-041
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	1200 mg	
<b>Pseudoephedrine Hydrochloride</b> (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Ps eudoephedrine Hydrochloride	120 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	22mm
Flavor		Imprint Code	Mucinex;1200
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824- 041-24	2 in 1 CARTON	06/26/2012	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824- 041-71	24 in 1 CARTON	06/26/2012	07/10/2017
2		1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:63824- 041-36	3 in 1 CARTON	06/26/2012	09/12/2017
3		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
А	NDC:63824-	1 :- 1 CADTON	01/01/2020	

Marketing Category	Citation NDA021585	<b>Date</b> 06/26/2012	Date
	Citation	Date	Date
	Application Number or Monograph	Marketing Start	Marketing End
Marketing Information			
4	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022 RB Health (US) LLC