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- FDA PI

Mucinex D Maximum Strength: Package Insert / Prescribing Info

Package insert / product label

Generic name: guaifenesin and pseudoephedrine hydrochloride

Dosage form: tablet, extended release

Medically reviewed by Drugs.com. Last updated on Aug 24, 2023.

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Drug Facts

| Active ingredients (in each extended-release bi-layer tablet) | Purposes |
|---|--------------------|
| Guaifenesin 1200 mg | Expectorant |
| Pseudoephedrine HCl 120 mg | Nasal Decongestant |

Indications and Usage for Mucinex D Maximum Strength

- 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:
 - o common cold
 - hay fever
 - o 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.

Mucinex D Maximum Strength Dosage and Administration

- · 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

Storage and Handling

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

 $\text{HOUR}_{\mathbb{R}}$

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

24

EXTENDED-RELEASE BI-LAYER TABLETS



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 |
| Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F) | Pseudoephedrine Hydrochloride | 120 mg |

Inactive Ingredients

Ingredient Name Strength

 $\textbf{carbomer homopolymer type B (allyl pentaerythritol crosslinked)} \ (UNII: \ HHT01ZNK31)$

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 | | |
| 4 | NDC:63824-041- | 1 in 1 CARTON | 01/01/2020 | |

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12 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

Labeler - RB Health (US) LLC (081049410)

More about Mucinex D Maximum Strength (guaifenesin / pseudoephedrine)

- · Check interactions
- Compare alternatives
- Pricing & coupons
- Reviews (21)
- Side effects
- Dosage information
- During pregnancy
- En español

Patient resources

• Mucinex D Max Strength drug information

Other formulations

Mucinex

Related treatment guides

Cough and Nasal Congestion

Medical Disclaimer

DRUG STATUS

Availability

Rx and/or OTC

Pregnancy & Lactation

Risk data available

CSA Schedule*

N/A Not a controlled drug

WADA Class

Anti-Doping Classification

User Reviews & Ratings

4.8 / 10

21 Reviews

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