# MUCINEX DM- dextromethorphan hydrobromide and guaifenesin tablet, extended release

**Mechanical Servants LLC** 

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**Mucinex®** 

DM

**Drug Facts** 

| Active ingredients (in each extended-<br>release bi-layer tablet) | Purpose           |
|---|-------------------|
| Dextromethorphan HBr 30 mg  | Cough suppressant |
| Guaifenesin 600 mg  | Expectorant       |

#### Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

### **Warnings**

#### Do not use

- for children under 12 years of age
- 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

- 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

 cough lasts more than 7 days, comes back, or occurs with 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 or 2 tablets every 12 hours; not more than
   4 tablets in 24 hours
- children under 12 years of age: do not use

#### Other information

- store at 20-25°C (68-77°F)
- tamper evident: do not use if carton is open or if pouch is broken or torn

# **Inactive ingredients**

carbomer homopolymer type B; D&C yellow #10 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:

R B Health (US), Parsippany, NJ 07054-0224

#### PRINCIPAL DISPLAY PANEL - 2 Tablet Pouch

Mucinex® DM

600 mg guaifenesin & 30 mg dextromethorphan HBr extended-release bi-layer tablets

#### **EXPECTORANT & COUGH SUPPRESSANT**

12

HOUR ®

- Controls Cough
- Thins And Loosens Mucus

2

extended-release bi-layer tablets







## PRINCIPAL DISPLAY PANEL-2 Tablet Pouch 4ct Package

#### Mucinex® DM

600 mg guaifenesin & 30 mg dextromethorphan HBr extended-release bi-layer tablets

#### **EXPECTORANT & COUGH SUPPRESSANT**

12 HOUR ®

Controls Cough
Thins And Loosens Mucus

# 4 Extended-Release Bi-layer Tablets

(2 Pouches: 2 tablets each)



## **MUCINEX DM**

dextromethorphan hydrobromide and guaifenesin tablet, extended release

| Product Information     |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:29485-6647 |
| Route of Administration | ORAL           |                    |                |

| Active Ingredient/Active Moiety  |                                  |          |  |
|--|----------------------------------|----------|--|
| Ingredient Name  | Basis of Strength                | Strength |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 30 mg    |  |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                               | GUAIFENESIN                      | 600 mg   |  |

| Inactive Ingredients   |          |  |  |
|--|----------|--|--|
| Ingredient Name  | Strength |  |  |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31) |          |  |  |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)   |          |  |  |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)                                       |          |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)  |          |  |  |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)                                      |          |  |  |

| Product Characteristics |                          |              |             |  |
|-------------------------|--------------------------|--------------|-------------|--|
| Color                   | white (yellow and white) | Score        | no score    |  |
| Shape                   | OVAL                     | Size         | 16mm        |  |
| Flavor                  |                          | Imprint Code | Mucinex;600 |  |
| Contains                |                          |              |             |  |

| P | Packaging            |   |                         |                       |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code            | Package Description                             | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:29485-<br>6647-1 | 1 in 1 BLISTER PACK                             | 06/26/2012              |                       |
| 1 |                      | 2 in 1 POUCH; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| NDA                   | NDA021620                                   | 06/26/2012              |                       |
|                       |   |                         |                       |

# **MUCINEX DM**

dextromethorphan hydrobromide and guaifenesin tablet, extended release

| <b>Product Information</b> |                |                    |                |
|----------------------------|----------------|--------------------|----------------|
| Product Type               | HUMAN OTC DRUG | Item Code (Source) | NDC:29485-6942 |
| Route of Administration    | ORAL           |                    |                |

| Active Ingredient/Active Moiety                                |                                  |          |  |
|--|----------------------------------|----------|--|
| Ingredient Name  | Basis of Strength                | Strength |  |
|  | DEXTROMETHORPHAN<br>HYDROBROMIDE | 30 mg    |  |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN                      | 600 mg   |  |

| Inactive Ingredients   |          |  |  |
|--|----------|--|--|
| Ingredient Name  | Strength |  |  |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31) |          |  |  |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)   |          |  |  |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)                                       |          |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)  |          |  |  |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)                                      |          |  |  |

| Product Characteristics |                          |              |             |  |
|-------------------------|--------------------------|--------------|-------------|--|
| Color                   | white (yellow and white) | Score        | no score    |  |
| Shape                   | OVAL                     | Size         | 16mm        |  |
| Flavor                  |                          | Imprint Code | Mucinex;600 |  |
| Contains                |                          |              |             |  |
|                         |                          |              |             |  |

| P | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code            | Package Description                             | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:29485-<br>6942-4 | 2 in 1 BLISTER PACK                             | 07/17/2017              |                       |  |
| 1 |                      | 2 in 1 POUCH; Type 0: Not a Combination Product |                         |                       |  |

| Marketing Information |   |                         |                       |  |  |
|-----------------------|---|-------------------------|-----------------------|--|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| NDA                   | NDA021620                                   | 07/17/2017              |                       |  |  |
|                       |   |                         |                       |  |  |

# Labeler - Mechanical Servants LLC (005530951)

| Establishment           |         |           |  |  |  |
|-------------------------|---------|-----------|--|--|--|
| Name                    | Address | ID/FEI    | Business Operations  |  |  |
| Mechanical Servants LLC |         | 005530951 | repack(29485-6647, 29485-6942) , relabel(29485-6647, 29485-6942) |  |  |

Revised: 12/2021 Mechanical Servants LLC