**MUCUS RELIEF DM AND OVERNIGHT COLD AND FLU- dextromethorphan hbr, guaifenesin, acetaminophen and triprolidine hcl**
**WALGREENS CO**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Maximum Strength Mucus Relief DM and Overnight Cold & Flu Value Pack**

***Drug Facts***

| ***Active ingredients (in each 20 mL)*** **Maximum Strength Mucus Relief DM Max** | ***Purposes*** |
|---|---|
| Dextromethorphan HBr 20 mg | Cough suppressant |
| Guaifenesin 400 mg | Expectorant |

| ***Active ingredients (in each 20 mL)*** **Nighttime Cold & Flu** | ***Purposes*** |
|---|---|
| **Acetaminophen 650 mg** | **Pain reliever/fever reducer** |
| Dextromethorphan HBr 20 mg | Cough suppressant |
| Triprolidine HCl 2.5 mg | Antihistamine |

**Uses**

**MAXIMUM STRENGTH MUCUS RELIEF DM**

- 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 imitants
    - the intensity of coughing
    - the impulse to cough to help you get to sleep

**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**

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

**When using this product do not use more that directed**

***Stop use and ask a doctor if***

- cough lasts more than 7 days comes back or occurs with fever, rash or headache that lasts. These could be sings of a serious condition.

**If pregnancy 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 Centre right away at 1-800-222-1222

**Directions**

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter
- **adults and children 12 years and older:** 20 mL every 4 hours
- **children under 12 years of age:** Do not use

**Other information**

- each 20 mL contains: **sodium 8 mg**
- low sodium
- store at room temperature
- do not refrigerate
- dosing cup provided

**Inactive ingredients (Maximum strength mucus relief DM)**

anhydrous citric acid, edetate disodium, FD&C Blue No.1, FD&C Red No. 40, flavors, potassium citrate, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

**Uses (Nighttime Cold and Flu)**

- temporarily relieves these common cold and flu symptoms:
- cough
- minor aches and pains
- sore throat
- headache
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

**Warnings**

**Liver warnings:** This product contains acetaminophen. Severe liver damage may occur if you take\

- more than 4000 mg in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

**If pregnant or breast feeding**

Ask a health professional before use

**Keep Out of Reach of Children**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Centre right away at 1-800-222-1222.

Quick medical attention is critical for adults as well as for children, even if you do not notice any signs

**Directions**

- **do not take more than directed (see overdose warnings**
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- **adults and children 12 years of age and older:** 20 ml in dosing cup provided every 4 hours
- **children under 12 years of age:** do not use

***Other Information***

- **each 20 mL contains:** sodium 10 mg
- low sodium
- store at room temperature

- do not refrigerate

**Inactive ingredients (Overnight Cold & Flu)**

anhydrous citric acid, ascorbic acid, edetate disodium, FD&C Blue No. 1, FD&C Red No. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

**Questions or comments?**

**(1-866-467-2748)**

**PRINCIPAL DISPLAY PANEL - Kit Carton**

**VALUE PACK**

NDC 0363-3998-12

**Compare to the active ingredients Maximum Strength Mucinex® Fast Max® DM Max***

**Mucus Relief DM**

Dextromethorphan HBr • Cough Suppressant
Guaifenesin • Expectorant
MAXIMUM STRENGTH

MULTI-SYMPTOM

- **Relieves chest congestion & cough**
- **Thins & loosens mucus**
- **4 hour dosing**
- **12 years & older**

*This product is not manufactured or distributed by Reckitt Benckiser, the distributor of Maximum Strength Mucinex® Fast-Max® DM Max.

**Compare to Mucinex® Nightshift Cold & Flu Active Ingredients****

**Nighttime Cold & Flu**

**ACETAMINOPHEN** • PAIN RELIEVER/FEVER REDUCER
DEXTROMETHORPHAN HBR • COUGH SUPPRESSANT

TRIPROLIDINE HCL • ANTIHISTAMINE

**MULTI-SYMPTOM**

**Maximum Strength per 4-hour dose**

- **Nighttime relief for a better morning**
- **Relieves cough, fever, sore throat, runny nose & sneezing**
- **Maximum Strength per 4-hour dose**
- **12 years & older**

**2 – 6 FL OZ (180 mL) BOTTLES / TOTAL 12 FL OZ (360 mL)**

**††These product is not manufactured or distributed by Reckitt Benckister Health, distributor of Maximum Strength Mucinex® Fast Max© DM Max & Mucinex© Nightshift Cold & Flu.**

**TAMPER EVIDENT: DO NOT TAKE MAXIMUM STRENGTH MUCUS RELIEF DM & OVERNIGHT COLD & FLU LIQUIDS AT THE SAME TIME.**

**Walgreens Pharmacist Recommended**

**Walgreens Pharmacist Survey**

**See bottle for full labeling.**


# MUCUS RELIEF DM AND OVERNIGHT COLD AND FLU

dextromethorphan hbr, guaifenesin, acetaminophen and triprolidine hcl kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0363-3998 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0363-3998-12 | 1 in 1 CARTON; Type 0: Not a Combination Product | 03/30/2020 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 1 BOTTLE | 180 mL |
| **Part 2** | 1 BOTTLE | 180 mL |

## Part 1 of 2

# MAXIMUM STRENGTH MUCUS RELIEF DM

dextromethorphan hbr and guaifenesin solution

### Product Information

| | |
|---|---|
| **Route of Administration** | ORAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Dextromethorphan Hydrobromide** (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS) | Dextromethorphan Hydrobromide | 20 mg in 20 mL |
| **Guaifenesin** (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ) | Guaifenesin | 400 mg in 20 mL |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **FD&C Blue No. 1** (UNII: H3R47K3TBD) | |
| **FD&C Red No. 40** (UNII: WZB9127XOA) | |
| **POTASSIUM CITRATE** (UNII: EE90ONI6FF) | |
| **propylene glycol** (UNII: 6DC9Q167V3) | |
| **propyl gallate** (UNII: 8D4SNN7V92) | |
| **water** (UNII: 059QF0KO0R) | |
| **sodium benzoate** (UNII: OJ245FE5EU) | |
| **sorbitol** (UNII: 506T60A25R) | |
| **sucralose** (UNII: 96K6UQ3ZD4) | |
| **xanthan gum** (UNII: TTV12P4NEE) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BLUE | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 03/30/2020 | |

## Part 2 of 2

# OVERNIGHT COLD AND FLU

acetaminophen, dextromethorphan hbr and triprolidine hcl solution

### Product Information

| | |
|---|---|
| **Route of Administration** | ORAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Acetaminophen** (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D) | Acetaminophen | 650 mg in 20 mL |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg in 20 mL |
| **TRIPROLIDINE HYDROCHLORIDE** (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM) | TRIPROLIDINE HYDROCHLORIDE | 2.5 mg in 20 mL |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **anhydrous citric acid** (UNII: XF417D3PSL) | |
| **edetate disodium** (UNII: 7FLD91C86K) | |
| **FD&C Blue No. 1** (UNII: H3R47K3TBD) | |
| **FD&C Red No. 40** (UNII: WZB9127XOA) | |
| **glycerin** (UNII: PDC6A3C0OX) | |
| **propyl gallate** (UNII: 8D4SNN7V92) | |
| **propylene glycol** (UNII: 6DC9Q167V3) | |
| **water** (UNII: 059QF0KO0R) | |
| **sodium benzoate** (UNII: OJ245FE5EU) | |
| **SODIUM CITRATE, UNSPECIFIED FORM** (UNII: 1Q73Q2JULR) | |
| **sorbitol** (UNII: 506T60A25R) | |
| **sucralose** (UNII: 96K6UQ3ZD4) | |
| **xanthan gum** (UNII: TTV12P4NEE) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BLUE | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | | 180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | | |

## Marketing Information

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|---|---|---|---|
| OTC monograph final | part341 | 03/30/2020 | |


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| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 03/30/2020 | |


## Labeler - WALGREENS CO (008965063)

Revised: 1/2022 WALGREENS CO