**CVS MAXIMUM STRENGTH SEVERE CONGESTION AND COUGH OVERNIGHT COLD AND FLU CLEAR AND COOL- dextromethorphan hbr, guaifenesin, phenylephrine hcl, acetaminophen and triprolidine hcl**
**CVS**

*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 Severe Congestion & Cough and Overnight Cold & Flu Value Pack**

***Drug Facts***

| ***Active ingredients (in each 20 mL)*** | ***Purposes*** |
|---|---|
| **Maximum Strength Severe Congestion & Cough** | |
| Dextromethorphan HBr 20 mg | Cough suppressant |
| Guaifenesin 400 mg | Expectorant |
| Phenylephrine HCl 10 mg | Nasal decongestant |

| ***Active ingredients (in each 20 mL)*** | ***Purposes*** |
|---|---|
| **Overnight Cold & Flu Clear & Cool** | |
| **Acetaminophen 650 mg** | **Pain reliever/fever reducer** |
| Dextromethorphan HBr 20 mg | Antihistamine/cough suppressant |
| Phenylephrine HCl 10 mg | Nasal decongestant |
| Triprolidine HCl 2.5 mg | Antihistamine |

**Uses**

**MAXIMUM STRENGTH SEVERE CONGESTION & COUGH**

- 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
    - nasal congestion due to a cold
    - temporarily helps you cough less

**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 that occurs with too much phlegm (mucus)

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

**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 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 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 6 mg
- low sodium
- store at room temperature
- do not refrigerate
- dosing cup provided

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

anhydrous citric acid, D&C Yellow No. 10, edetate disodium, FD&C Blue No.1, flavors, potassium citrate, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

**Uses (OVERNIGHT COLD & FLU CLEAR & COOL**

- temporarily relieves these common cold and flu symptoms:
- cough
- nasal congestion
- 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 over:** 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
- store at room temperature
- do not refrigerate

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

anhydrous citric acid, ascorbic acid, D&C Yellow No. 10, edetate disodium, FD&C Blue No. 1, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose and xanthan gum

**Questions or comments?**

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

**PRINCIPAL DISPLAY PANEL - Kit Carton**

**VALUE PACK**

NDC 69842-967-12

Compare to Mucinex® Fast Max® DM Maximum Strength Severe Congestion & Cough Clear & Cool™ Active Ingredients*

**Maximum Strength**

**Severe Congestion & Cough**

Dextromethorphan HBr • Cough Suppressant
Guaifenesin • Expectorant

Phenylephrine HCl • Nasal Decongestant

- **Controls Cough**
- **Relieves Nasal & Chest Congestion**
- **Thins & Loosens Mucus**

**Cooling Menthol Flavor**

Naturally and Artificially Flavored

**For Ages 12+**

**6 FL. OZ. (180 mL)**

*This product is not manufactured or distributed by Reckitt Benckiser, the distributor of Mucinex® Fast-Max® Maximum Strength Severe Congestion & Cough Clear & Cool™

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

**Overnight Cold & Flu**

**Clear & Cool**

**Acetaminophen** • Pain Reliever/Fever Reducer
Dextromethorphan HBr • Cough Suppressant
Phenylephrine HCl • Nasal Decongestant

Triprolidine HCl • Antihistamine

**Maximum Strength per 4-hour dose**

**Night Time Relief for a Better Morning**

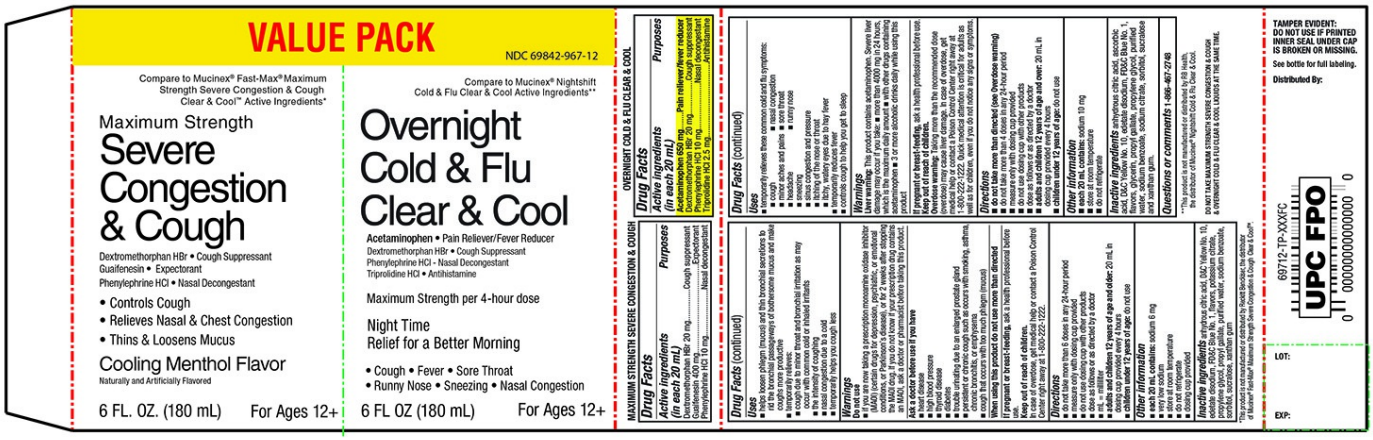
- **Cough**
- **Fever**
- **Sore Throat**
- **Runny Nose**
- **Sneezing**
- **Nasal Congestion**

**For Ages 12+**

**6 FL OZ (180 mL)**

**This product is not manufactured or distributed by RB Health, the distributor of Mucinex® Nightshift Cold & Flu Clear & Cool.

**DO NOT TAKE MAXIMUM STRENGTH SEVERE CONGESTION & COUGH & OVERNIGHT COLD & FLU CLEAR & COOL LIQUIDS AT THE SAME TIME.**




# CVS MAXIMUM STRENGTH SEVERE CONGESTION AND COUGH OVERNIGHT COLD AND FLU CLEAR AND COOL

dextromethorphan hbr, guaifenesin, phenylephrine hcl, acetaminophen and triprolidine hcl kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69842-967 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:69842-967-12 | 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 SEVERE CONGESTION AND COUGH

dextromethorphan hbr, guaifenesin and phenylephrine hcl 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 |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg in 20 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **FD&C Blue No. 1** (UNII: H3R47K3TBD) | |
| **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** | GREEN | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | MENTHOL (COOLING MENTHOL) | **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

# CVS OVERNIGHT COLD AND FLU CLEAR AND COOL

acetaminophen, dextromethorphan hbr, phenylephrine hcl 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 |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 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) | |
| **ASCORBIC ACID** (UNII: PQ6CK8PD0R) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **edetate disodium** (UNII: 7FLD91C86K) | |
| **FD&C Blue No. 1** (UNII: H3R47K3TBD) | |
| **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** | GREEN | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | MENTHOL (COOLING MENTHOL) | **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 | |


## Marketing Information

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


## Labeler - CVS (062312574)

Revised: 4/2020 CVS