# MULTI SYMPTOM COLD AND MULTI SYMPTOM NIGHTTIME COLD CHILDRENS-dextromethorphan hbr, guaifenesin, phenylephrine hci, acetaminophen, diphenhydramine hci, phenylephrine hci CVS Pharmacy

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#### **DRUG FACTS**

# Active ingredients for Nighttime (in each 10 mL)

Acetaminophen 325 mg
Diphenhydramine HCI 12.5 mg
Phenylephrine HCI 5 mg

# Active ingredients for Daytime (in each 5 mL)

Dextromethorphan HBr 5 mg
Guaifenesin 100 mg
Phenylephrine HCl 2.5 mg

# **Purpose for Nighttime**

#### Pain reliever / fever reducer

Antihistamine / Cough suppressant
Nasal Decongestant

# **Purpose for Daytime**

Cough suppressant Expectorant

Nasal decongestant

#### Uses

# **Nighttime**

- temporarily relieves these common cold and flu symptoms
- minor aches and pains
- headache
- sore throat
- sneezing
- runny nose
- nasal congestion

- cough
- controls cough to help your child get to sleep
- temporarily reduces fever

#### **Daytime**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make cough more productive
- temporarialy 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 your child get to sleep
  - nasal congestion due to a cold
  - stuffy nose

# Warnings

#### **NIGHTTIME**

**Liver warning**: This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**Allergy alert**: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Sore throat warning**: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Do not use

# **Nighttime**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- in a child who is taking 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product
- with any other drug containing diphenhydramine, even one used on skin.
- If your child is allergic to acetaminophen or any of the inactive ingredients in this product

• to make a child sleepy

#### **Daytime**

 in a child who is taking a prescription monoamine oxidase inhibitor (MAOI)(certain drugs for depression,psychiatic 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 giving this product.

# Ask a doctor before use if you have

#### **Nighttime**

- liver disease
- heart disease
- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

#### **Daytime**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

# Ask a doctor or pharmacist before use if you are

# **Nighttime**

- taking the blood thinning drug warfain
- taking sedative or tranquilizers

# When using these products

# **Nighttime**

- do not use more than directed
- marked drowsiness may occur
- excitablity may occur, especially in children
- sedatives and tranquilizer may increase drowsiness

# **Daytime**

do not use more than directed

# Stop use and ask a doctor if

# **Nighttime**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or last more than 5 days

- redness or swelling is present
- new symptoms occurs
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with rash or headache that lasts. These could be signs
  of a serious conditions.

### **Daytime**

- nervousness, dizziness or sleeplessness occur
- symptoms do not better within 7 days or occur with fever
- cough lasts more than 7 days, comes back or occur with a fever, rash, or headache that lasts. These could be signs of a serious condition.

# Keep out of reach of children.

#### **Nighttime**

**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 Center right away (1-800-222-1222). Quick medical attention is critical even if you do not notice any sign or symptoms.

# **Daytime**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### **Directions**

# **Nighttime**

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see Overdose warning)
- do not give more than 5 doses in any 24-hour period
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 days unless directed by a doctor
- measure only with dosing cup provided. Do not use any other dosing device.
- ml = milliliter
- dose as follows or as directed by a doctor
- children 6 to under 12 years of age: 10 mL every 4 hours
- children under 6 years of age: do not use

# **Daytime**

- do not take more than 6 doses in any 24-hours period
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device
- keep dosing cup with product
- dose as follows, or as directed by a doctor
- mL = milliliter

| Age | Dose |
|-----|------|

| children 6 years to under 12 years | 10 mL every 4 hours |  |
|------------------------------------|---------------------|--|
| children 4 years to under 6 years  | 5 mL every 4 hours  |  |
| children under 4 years             | do not use          |  |

#### Other information

# **Nighttime**

- each 10 mL contains: sodium 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

# **Daytime**

- each 5 mL contains: 4 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

# **Inactive ingredients**

#### **Nighttime**

citric acid, disodium EDTA, FD&C Blue #1, FD&C red #40, Flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

# **Daytime**

citric acid, disodium EDTA, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose xanthan gum

#### Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

Compare to the active ingredients in Children's Mucinex® Night Time Multi-Symptom Cold\*\*

#### Children's

multi-symptom

Nighttime Cold

ACETAMINOPHEN 325 mg (pain reliever / fever reducer)

DIPHENHYDRAMINE HCI 12.5 mg (Antihistamine-Cough Suppressant)

PHENYLEPHRINE HCI 5 mg (Nasal Decongestant)

Relieves:

Nasal and chest congestion

Reduces fever

Soothes cough and sore throat

Berry Flavor Liquid

Dosage Cup Included

Ages 6 - 11 Years

FL OZ (mL)

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

# TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

\*\*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Children's Mucinex® Night Multi-Symptom Time Cold

#### **DAYTIME**

Compare to active ingredients in Children's Mucinex® Multi-Symptom Cold\* Children's

#### multi-symptom cold

DEXTROMETHORPHAN HBr 5 mg (Cough Suppressant)

GUAIFENESIN 100 mg (expectorant)

PHENYLEPHRINE HCI 2.5 mg (Nasal Decongestant)

Relieves:

Nasal and chest congestion

Soothes cough

Thins and loosens mucus

Berry Flavor Liquid

Dosage cup included

Ages 4 to 11 years

# FL OZ (mL)

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

1-800-SHOP CVS

#### **Product Label**



CVS HEALTH Children's Multi-Symptom Nighttime Cold Children's Multi-Symptom Cold

# MULTI SYMPTOM COLD AND MULTI SYMPTOM NIGHTTIME COLD CHILDRENS

dextromethorphan hbr, guaifenesin, phenylephrine hci, acetaminophen, diphenhydramine hci, phenylephrine hci kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-820

| P | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code            | Package Description                           | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:69842-820-<br>08 | 1 in 1 KIT; Type 0: Not a Combination Product | 02/28/2017              | 02/28/2025            |  |

# Quantity of Parts Part # Package Quantity Total Product Quantity Part 1 1 BOTTLE, PLASTIC 118 mL Part 2 1 BOTTLE, PLASTIC 118 mL

# Part 1 of 2

# **MULTI SYMPTOM COLD DAYTIME CHILDRENS**

dextromethorphan hbr, guaifenesin, phenylephrine hci liquid

# **Product Information**

Item Code (Source) NDC:69842-607

**Route of Administration** ORAL

| Active Ingredient/Active Moiety  |                                  |                   |
|--|----------------------------------|-------------------|
| Ingredient Name  | <b>Basis of Strength</b>         | Strength          |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 5 mg<br>in 5 mL   |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                               | GUAIFENESIN                      | 100 mg<br>in 5 mL |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)            | PHENYLEPHRINE<br>HYDROCHLORIDE   | 2.5 mg<br>in 5 mL |

| Inactive Ingredients                        |          |  |
|---|----------|--|
| Ingredient Name                             | Strength |  |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)    |          |  |
| EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF) |          |  |
| 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 (UNII: 1Q73Q2JULR)           |          |  |
| SORBITOL (UNII: 506T60A25R)                 |          |  |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                |          |  |
| XANTHAN GUM (UNII: TTV12P4NEE)              |          |  |

| Product Characteristics |       |              |  |
|-------------------------|-------|--------------|--|
| Color                   |       |              |  |
| Shape                   |       | Size         |  |
| Flavor                  | BERRY | Imprint Code |  |
| Contains                |       |              |  |

| P | ackaging                        |  |                         |                       |
|---|---------------------------------|--|-------------------------|-----------------------|
| # | # Item Code Package Description |  | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:69842-<br>607-04            | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |
|   |                                 |  |                         |                       |

# Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC Monograph DrugM01202/28/201702/28/2025

# Part 2 of 2

# **MULTI SYMPTOM NIGHTTIME COLD CHILDRENS**

acetaminophen, diphenhydramine hci, phenylephrine hci liquid

# Product Information Item Code (Source) NDC:69842-606 Route of Administration ORAL

| Active Ingredient/Active Moiety   |                                  |                     |
|---|----------------------------------|---------------------|
| Ingredient Name   | <b>Basis of Strength</b>         | Strength            |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)                          | ACETAMINOPHEN                    | 325 mg<br>in 10 mL  |
| <b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE<br>HYDROCHLORIDE | 12.5 mg<br>in 10 mL |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)           | PHENYLEPHRINE<br>HYDROCHLORIDE   | 5 mg<br>in 10 mL    |

| Inactive Ingredients                        |          |  |  |
|---|----------|--|--|
| Ingredient Name                             | Strength |  |  |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)    |          |  |  |
| EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF) |          |  |  |
| 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 (UNII: 1Q73Q2JULR)           |          |  |  |
| SORBITOL (UNII: 506T60A25R)                 |          |  |  |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                |          |  |  |
| XANTHAN GUM (UNII: TTV12P4NEE)              |          |  |  |
|   |          |  |  |

| Product Characteristics |       |              |  |
|-------------------------|-------|--------------|--|
| Color                   |       |              |  |
| Shape                   |       | Size         |  |
| Flavor                  | BERRY | Imprint Code |  |

# Contains

| l | Packaging |                      |  |                         |                       |
|---|-----------|----------------------|--|-------------------------|-----------------------|
|   | #         | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
|   | 1         | NDC:69842-<br>606-04 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |

|   | Marketing Information |                         |                       |            |
|---|-----------------------|-------------------------|-----------------------|------------|
| Marketing Application Number or Monograph Category Citation |                       | Marketing Start<br>Date | Marketing End<br>Date |            |
|   | OTC Monograph Drug    | M012                    | 02/28/2017            | 02/28/2025 |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC Monograph Drug    | M012  | 02/28/2017              | 02/28/2025            |
|                       |   |                         |                       |

# Labeler - CVS Pharmacy (062312574)

Revised: 3/2024 CVS Pharmacy