**CVS CHILDRENS NIGHTTIME MULTI SYMPTOM COLD- acetaminophen , diphenhydramine hydrochloride,phenylephrine hydrochloride liquid**
**CVS PHARMACY**

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**CVS Children's Nighttime Multi-Symptoms Cold 4 FL OZ (180 mL)**

***Drug Facts***

| ***Active ingredients (in each 10 mL)*** | ***Purposes*** |
|---|---|
| **Acetaminophen 325 mg** | **Pain reliever/fever reducer** |
| Diphenhydramine HCl 12.5 mg | Antihistamine/cough suppressant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

**Uses**

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

**Warnings**

**Liver Warning:**

This product contains acetaminophen. Severe liver damage may occur if you take:

- 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**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- To make child sleepy
- with any other drug containing diphenhydramine, even one used on the skin
- in a child who is 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 the child have**

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

**Ask a doctor or pharmacist before use if the child is**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

**When using this product**

- **do not use more than directed (see Overdose warning)**
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

**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 Center right away 1-800-222-1222. Quick medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

**Directions**

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see Overdose warning)**
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- children 6 years to 12 years of age: 10 mL in dosing cup provided every 4 hours while symptoms last; do not give more than 5 doses in 24-hours period
- children under 6 years of age: do not use

**Other information**

- each 10 mL contains: **sodium 4 mg**
- store at room temperature
- do not refrigerate

**Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, natural and artificial flavor, potassium citrate, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

**Questions or comments?**

**1-866-467-2748**

**PRINCIPAL DISPLAY PANEL**

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

NDC# 51316-733-04

**Children's**

**Night TimeMuti-Symptom Cold**

**Acetaminophen** Pain Reliever/Fever Reducer
Diphenhydramine HCl Antihistamine/Cough Suppressant
Phenylephrine HCl Nasal Decongestant

Relieves Stuffy Nose

Controls Cough

Relieves Fever & Sore Throat

Relieves Runny Nose & Sneezing

Dosing Cup Included

**For Ages 6 & Over**

**Very Berry Flavor**

Naturally and Artificially Flavored

4 FL OZ (118 mL)

*This product is not manufactured or distributed by RB Health (US), distributor Children's Mucinex® Nighttime Multi-Symptoms Cold..

**TAMPER EVIDENT: DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING.**

Distributed by:


# CVS CHILDRENS NIGHTTIME MULTI SYMPTOM COLD

acetaminophen , diphenhydramine hydrochloride,phenylephrine hydrochloride liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:51316-733 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |

| | | |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | in 10 mL |
| **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 12.5 mg in 10 mL |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg in 10 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** | RED | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | BERRY | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:51316-733-04 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/20/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M010 | 02/20/2023 | |

## Labeler - CVS PHARMACY (062312574)

Revised: 11/2023 CVS PHARMACY