

**MULTI SYMPTOM NIGHTTIME COLD- acetaminophen diphenhydramine hci
phenylephrine hci liquid
CVS Pharmacy**

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.

DRUG FACTS

Active ingredients (in each 10 mL)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever / fever reducer

Antihistamine / Cough suppressant

Nasal Decongestant

Uses

- 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

Warnings

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

- 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

Ask a doctor before use if you have

- 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)

Ask a doctor or pharmacist before use if you are

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

When using these products

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

Stop use and ask a doctor if

- 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.

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 even if you do not notice any sign or symptoms.

Directions

- **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

Other information

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

Inactive ingredients

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

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 HCl 12.5 mg (Antihistamine-Cough Suppressant)

PHENYLEPHRINE HCl 5 mg (Nasal Decongestant)

Relieves:

Nasal congestion

Reduces fever

Soothes cough and sore throat

Ages 6 to 11 Years

Berry Flavor Liquid

Dosage Cup Included

FL OZ (mL)

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

CVS.com® 1-800-SHOP CVS

Product Label

Drug Facts (continued)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
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 One CVS Drive, Woonsocket, RI 02895
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CVS Quality
 Money Back Guarantee



Package Contains One Bottle

Actual Size

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

NDC 69842-506-04

Children's Multi-Symptom Nighttime Cold

ACETAMINOPHEN 325 mg
 Pain reliever/Fever reducer

DIPHENHYDRAMINE HCl 12.5 mg
 Antihistamine/Cough suppressant

PHENYLEPHRINE HCl 5 mg
 Nasal decongestant

Relieves:
 Nasal congestion

Reduces fever Soothes cough & sore throat

Ages 6 to 11 Years




Mixed Berry Flavor
 Dosage cup included

Actual Bottle Size on Side Panel

4 FL OZ (118 mL)

Drug Facts

Active ingredients (in each 10 mL) **Purposes**

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- diabetes ■ thyroid disease ■ glaucoma
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#194343



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PLD-A032C F030307

Lot No:
 Exp. Date:

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

MULTI SYMPTOM NIGHTTIME COLD

acetaminophen diphenhydramine hci phenylephrine hci liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-506
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	PHENYLEPHRINE	5 mg

UNII:1WS297W6MV)

HYDROCHLORIDE

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: 059QF0KOOR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY (Mixed)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-506-04	1 in 1 BOX	04/30/2018	04/30/2025
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/30/2018	04/30/2025

Labeler - CVS Pharmacy (062312574)

Revised: 11/2022

CVS Pharmacy