

**COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hbr,  
triprolidine hcl solution  
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

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**CVS 44-063**

***Active ingredients (in each 20 mL)***

Acetaminophen 650 mg  
Dextromethorphan HBr 20 mg  
Triprolidine HCl 2.5 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Antihistamine

***Uses***

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

- 3 or more alcoholic drinks every day while using this product
- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen

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

- rash
- blisters
- skin reddening

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.
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if you have**

- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

**Ask a doctor or pharmacist before use if you are**

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

**When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- alcohol, sedatives, and tranquilizers may increase drowsiness
- marked drowsiness may occur
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages

**Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

**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 Center right away. Prompt medical attention is critical for adults as well as for children even if you do not

notice any signs or symptoms.

### ***Directions***

- **do not take more than directed**
- do not take more than 4 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

### ***Other information***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

### ***Inactive ingredients***

anhydrous citric acid, FD&C blue #1, FD&C red #40, FD&C yellow #6, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sucralose, xanthan gum

### ***Questions or comments?***

**1-800-426-9391**

### ***Principal Display Panel***

♥CVS  
Health®

Compare to the active  
ingredients in Mucinex®  
Nightshift® Cold & Flu\*

### **Nighttime**

### **Cold & Flu**

**ACETAMINOPHEN** - Pain reliever/Fever reducer  
**DEXTROMETHORPHAN HBr** - Cough suppressant  
**TRIPROLIDINE HCl** - Antihistamine

MULTI-SYMP TOM

Controls cough  
Relieves fever & sore throat  
Relieves runny nose & sneezing

**FOR AGES 12+**

**6 FL OZ (177 mL)**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY  
SEAL UNDER CAP IS BROKEN OR MISSING**

**PARENTS:**

**Learn about teen medicine abuse**

**[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)**

\*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Mucinex® Nightshift® Cold & Flu.

B-063-45 REV0423A

50844 REV0423A06345

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Compare to the active ingredients in Mucinex® Nightshift® Cold & Flu\*

# Nighttime Cold & Flu

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B-063-45 REV0423A  
50844 REV0423A06345

PEEL BACK TAB TO READ COMPLETE DRUG FACTS AND INFORMATION

**PARENTS:**  
Learn about teen medicine abuse  
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### Drug Facts

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

**Active ingredients (in each 20 mL)** **Purpose**  
 Acetaminophen 650 mg ..... Pain reliever/fever reducer  
 Dextromethorphan HBr 20 mg ..... Cough suppressant  
 Triprolidine HCl 2.5 mg ..... Antihistamine

**Uses** ■ temporarily relieves these common cold and flu symptoms: ■ headache ■ minor aches and pains  
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No Print / No Varnish Area  
Lot # and Exp. Info

### Drug Facts (continued)

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■ rash ■ blisters ■ skin reddening  
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### Drug Facts (continued)

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**Questions or comments?** 1-800-426-9391

CVS 44-063

## COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hbr, triprolidine hcl solution

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:51316-963

**Route of Administration**

ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>TRIPROLIDINE HYDROCHLORIDE</b> (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-963-45	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/23/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/23/2023	

**Labeler** - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

## Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.

967626305

manufacture(51316-963) , pack(51316-963)

Revised: 10/2024

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED