

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

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-SYMPTOM

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

*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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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

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 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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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
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
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

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: 10/2023

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED