

**NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr,  
doxylamine succinate liquid  
CVS PHARMACY, INC**

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**Drug Facts**

**Active ingredients (in each 30 mL)**

**Acetaminophen 650 mg**

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

**Purposes**

**Pain reliever/fever reducer**

Cough suppressant

Antihistamine

**Uses**

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - fever
  - runny nose and sneezing
  - cough due to minor throat and bronchial irritation

**Warnings**

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

- more than 4000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday while using this product

**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 is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### **Do not use**

- 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.
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

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

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

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

- sedatives or tranquilizers
- the blood thinning drug warfarin

### **When using this product**

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives and tranquilizers may increase drowsiness

### **Stop use and ask a doctor if**

- pain or cough gets worse or last more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be a signs of a serious conditions.

### **If pregnant or breast-feeding,**

ask a health professional before use.

### **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 (1-800-222-1222) right away. Quick 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 (see Overdose warning)
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- mL = milliliter
- keep dosing cup with product
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years of age: do not use
- **when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing**

## Other information

- **each 30 mL contains:** potassium 5 mg
- **each 30 mL contains:** sodium 24 mg
- store between 20-25°C (68-77°F). Do not refrigerate

## Inactive ingredients

acesulfame potassium, alcohol, citric acid, FD&C blue1, FD&C red 40, Flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

## Questions or comments?

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

## Principal Display Panel

Compare to the active ingredients in Vicks® NyQuil® Cold & Flu\*

Multi-Symptom

### Nighttime

ACETAMINOPHEN

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

DOXYLAMINE SUCCINATE

Antihistamine

Relieves

Headache, Fever, Sore throat, Minor aches & pains, Sneezing, Runny nose, Cough

COLD & FLU

Cherry flavor

Alcohol 10%

Ages 12+

FL OZ (mL)

\*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks® and NyQuil® are registered trademarks of The Procter & Gamble Company.

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

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

**Product Label**



Compare to the active ingredients in Vicks® NyQuil® Cold & Flu\*

NDC 51316-343-12

# Multi-Symptom Nighttime

## ACETAMINOPHEN

Pain reliever; Fever reducer

## DEXTROMETHORPHAN HBr

Cough suppressant

## DOXYLAMINE SUCCINATE

Antihistamine

Relieves:

Headache, Fever, Sore throat, Minor aches & pains, Sneezing, Runny nose, Cough

COLD & FLU



Cherry Flavor  
Alcohol 10%  
Ages 12+

12 FL OZ (355 mL)

PLD-A427B LB009891

### Drug Facts

Active ingredients (in each 30 mL)	Purposes
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine

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PLD-A427B LB009921

PEEL CORNER FOR MORE DRUG FACTS

### Drug Facts (continued)

#### Uses

- temporarily relieves these common cold/flu symptoms
  - minor aches and pains
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  - sore throat
  - runny nose and sneezing
  - fever
  - cough due to minor throat and bronchial irritation

#### Warnings

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

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

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

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

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#### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains

PEEL CORNER FOR MORE DRUG FACTS

### Drug Facts (continued)

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.

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### Drug Facts (continued)

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### Drug Facts (continued)

**Inactive ingredients** acesulfame potassium, alcohol, citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

#### Questions or comments?

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CVS HEALTH Multi-Symptom Nighttime Cold & Flu

NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-343
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	

## Product Characteristics

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51316-343-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2023	
2	NDC:51316-343-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2023	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	03/15/2023	

**Labeler** - CVS PHARMACY, INC (062312574)

Revised: 7/2024

CVS PHARMACY, INC