

**NIGHTTIME- acetaminophen, dextromethorphan hbr, doxylamine succinate solution**  
**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.*

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**CVS Pharmacy, Inc. Nighttime Cold & Flu Relief Drug Facts**

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

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

**Uses**

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

**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:

- 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.
- 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**

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

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

- taking sedatives or tranquilizers
- taking 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 lasts 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

signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** 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**

- take only as directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

|                                 |                   |
|---------------------------------|-------------------|
| adults & children 12 yrs & over | 30 mL every 6 hrs |
| children 4 to under 12 yrs      | ask a doctor      |
| children under 4 yrs            | do not use        |

**Other information**

- **each 30 mL contains:** sodium 39 mg
- store at 20-25°C (68-77°F)

**Inactive ingredients**

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

**Questions?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

CVS Health®

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:

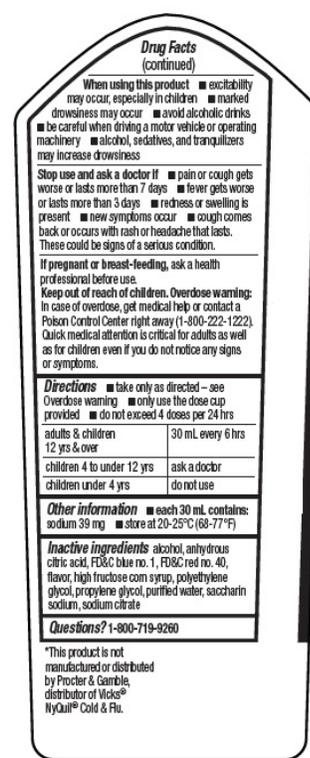
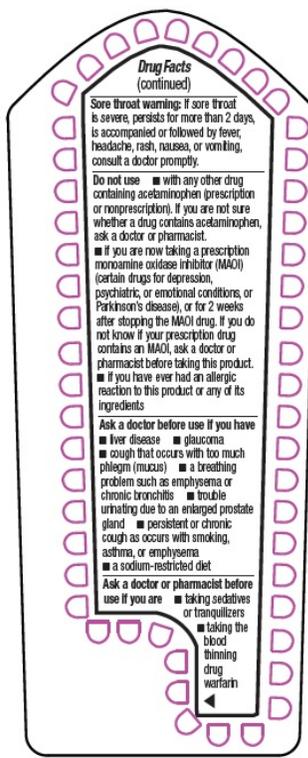
Aches, Fever, Sore throat, Cough, Sneezing, Runny nose

COLD & FLU

Cherry Flavor

ALCOHOL 10%

12 FL OZ (355 mL)



## NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:59779-459 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength             | Strength            |
|--|-------------------------------|---------------------|
| <b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                    | ACETAMINOPHEN                 | 650 mg<br>in 30 mL  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg<br>in 30 mL   |
| <b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)                | DOXYLAMINE SUCCINATE          | 12.5 mg<br>in 30 mL |

## Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| ALCOHOL (UNII: 3K9958V90M)                          |          |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)            |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                  |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                  |          |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)         |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                 |          |
| WATER (UNII: 059QF0KO0R)                            |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                 |          |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) |          |

## Product Characteristics

|          |                        |              |  |
|----------|------------------------|--------------|--|
| Color    | RED (Clear/Dark Red)   | Score        |  |
| Shape    |                        | Size         |  |
| Flavor   | CHERRY (Menthol Aroma) | Imprint Code |  |
| Contains |                        |              |  |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:59779-459-38 | 295 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/12/2011           | 10/01/2013         |
| 2 | NDC:59779-459-30 | 177 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/16/2011           | 09/16/2011         |
| 3 | NDC:59779-459-50 | 2 in 1 PACKAGE  | 08/19/2011           |                    |
| 3 |                  | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 4 | NDC:59779-459-34 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/05/2012           |                    |
| 5 | NDC:59779-459-40 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/19/2011           |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 08/12/2011           |                    |

**Labeler** - CVS Pharmacy (062312574)