

**CVS NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan  
hbr, doxylamine succinate solution  
CVS PHARMACY**

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**CVS 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 doses in 24 hours, which is the maximum daily amount for this product
- 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
- 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 16 mg
- store at room temperature and do not refrigerate

**Inactive ingredients**

anhydrous citric acid, D&C Yellow No. 10, disodium edetate, FD&C Green No. 3, FD & C Yellow No 6, flavors, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol liquid, sucralose.

**Questions or comments?**

**1-866-467-2748**

**Package/Label Principal Display Panel**

Compare to the active ingredients in VICKS® Nyquil™ Cold & Flu\*

NDC 51316-692-12

**Nighttime Cold & Flue Relief**

**Acetaminophen,** Dextromethorphan succinate,

Doxylamine HBr

Headache, Fever, Sore Throat

Minor Aches & Pains

Sneezing, Runny Nose, Cough

# Original Flavor

12 FL OZ (354 mL)

## Distributed by:

**\*This product is not manufactured or distributed by Procter & Gamble, the distributor of Vicks® Nyquil™ Cold & Flu\***

7.75" Width

3.5" Height

**Drug Facts (continued)**

**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.** In case of overdose, get medical help or contact a Poison Control Center right away at 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 • 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 16 mg • store at room temperature and do not refrigerate

**Inactive ingredients** citric acid, D&C Yellow No. 10, disodium edetate, FD&C Green No. 3, FD&C Yellow No. 6, flavors, xanthan gum, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol liquid, sucralose.

**Questions or comments?** 1-866-467-2748

LOT: 6920R6120VSR

UNVARNISHED AREA

EXP:

Distributed by:  
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One CVS Drive  
Woonsocket, RI 02895  
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Original Seal Indicated Over

PLASTIC BOTTLE PLASTIC CUP

Not for Sale in California



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**

Original Flavor

12 FL OZ (354 mL)

**Drug Facts** **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN.**

Active ingredients (in each 30 mL)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine succinate 12.5 mg	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 doses in 24 hours, which is the maximum daily amount for this product • 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.

**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 an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** • taking sedatives or tranquilizers • taking the blood thinning drug warfarin

## CVS NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-692
<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 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

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	

<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)
<b>SORBITOL</b> (UNII: 506T60A25R)
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-692-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/13/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	02/13/2023	

**Labeler -** CVS PHARMACY (062312574)

Revised: 11/2023

CVS PHARMACY