

## **NIGHTTIME- acetaminophen, dextromethorphan hydrobromide and doxylamine succinate liquid**

**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 dose cup)**

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. The maximum daily dose of this product is 4 doses (2,600 mg acetaminophen) in 24 hours. 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

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is 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.

- to make a child sleepy
- 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.**

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 Liver warning

- use dose cup
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL (2 TBSP) every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

**Other information**

- each 30 mL dose cup 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 or comments?**

1-800-719-9260

**Package/Label Principal Display Panel**

Compare to the active ingredients in Vicks® NyQuil®

PAIN RELIEVER, FEVER REDUCER, COUGH SUPPRESSANT, ANTIHISTAMINE

NIGHTTIME

COLD/FLU RELIEF

CHERRY FLAVOR

Multi-Symptom

Acetaminophen – aches, fever, sore throat

Dextromethorphan HBr – cough

Doxylamine Succinate – sneezing, runny nose

8 FL OZ (237 mL)

ALCOHOL 10%

**DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil®.

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 www.cvs.com 1-800-shop-CVS  
 V-6440



#890819



: 45934 17 F2



NDC 59779-459-34  
 Compare to the active ingredients in Vicks® NyQuil®\*

**PAIN RELIEVER, FEVER REDUCER,  
 COUGH SUPPRESSANT, ANTIHISTAMINE**

**NIGHTTIME  
 COLD/FLU RELIEF**

**CHERRY FLAVOR**

**Multi-Symptom**

**Acetaminophen**.....aches, fever, sore throat  
**Dextromethorphan HBr**.....cough  
**Doxylamine Succinate**.....sneezing, runny nose

**8 FL OZ (237 mL) ALCOHOL 10%**

**Drug Facts**

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

Active ingredients (in each 30 mL dose cup)	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  
 ■ runny nose and sneezing ■ headache ■ fever  
 ■ minor aches and pains ■ sore throat

**Warnings**

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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 acetaminophen, ask a doctor or pharmacist.

**PEEL BACK AT CORNER FOR MORE INFORMATION** →

**Drug Facts (continued)**

- 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. ■ to make a child sleepy
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 These could be signs of a serious condition. ▶

**Drug Facts (continued)**

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**Questions or comments?** 1-800-719-9260

**NIGHTTIME**

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

**Product Information**

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

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (DOXYLAMINE)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

**Inactive Ingredients**

Ingredient Name	Strength
ALCOHOL	
ANHYDROUS CITRIC ACID	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
HIGH FRUCTOSE CORN SYRUP	
POLYETHYLENE GLYCOLS	
PROPYLENE GLYCOL	
WATER	
SACCHARIN SODIUM	
SODIUM CITRATE	

**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		
2	NDC:59779-459-30	177 mL in 1 BOTTLE		
3	NDC:59779-459-40	355 mL in 1 BOTTLE		
4	NDC:59779-459-34	237 mL in 1 BOTTLE		
5	NDC:59779-459-50	2 in 1 CARTON		
5		355 mL in 1 BOTTLE		

**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)