

**COLD AND FLU RELIEF NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid**  
**Rite Aid Corporation**

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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
  - fever
  - sore throat
  - 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 4,000 doses 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.

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

- liver disease
- glaucoma
- 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
- cough that occurs with too much phlegm (mucus)

### **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 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:** 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-hours 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 Day Time or Night Time 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, D&C yellow #10, FD&C green #3, FD&C yellow #6,, 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 and Flu\*

NIGHTTIME

COLD & FLU RELIEF

ACETAMINOPHEN 650 mg

DEXTROMETHORPHAN HBr 30 mg

DOXYLAMINE SUCCINATE 12.5 mg

PAIN RELIEVER / FEVER REDUCER

COUGH SUPPRESSANT

ANTIHISTAMINE

Relieves headache, fever, sore throat, minor aches & pains

Sneezing • Runny nose • Cough

10% Alcohol

For ages 12 years & over

Nighttime relief

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:

RITE AID, 30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

### Product Label

NDC 11822-5832-2 Compare to the active ingredients in Vicks® NyQuil® Cold & Flu\*

# NIGHTTIME COLD & FLU RELIEF

**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**

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- 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**

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- 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 blue #1, 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  
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**PARENTS:** Learn about teen medicine abuse  
www.StopMedicineAbuse.org

DISTRIBUTED BY: RITE AID  
30 HUNTER LANE, CAMP HILL, PA 17011  
www.riteaid.com

SATISFACTION GUARANTEE:  
If you're not satisfied,  
we'll happily refund your money.

**ACETAMINOPHEN 650 mg**  
**DEXTROMETHORPHAN HBr 30 mg**  
**DOXYLAMINE SUCCINATE 12.5 mg**

PAIN RELIEVER / FEVER REDUCER  
COUGH SUPPRESSANT  
ANTIHISTAMINE

Relieves headache, fever, sore throat,  
minor aches & pains  
Sneezing • Runny nose • Cough

10% Alcohol

**CHERRY FLAVOR**

For ages 12 years & over

12 FL OZ (355 mL)

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

Active ingredients (in each 30 mL)	Purposes
Acetaminophen 650 mg	Pain reliever/fever reducer
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- 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
- taking the blood thinning drug warfarin

**RITE AID Night time Cold & Flu**

## COLD AND FLU RELIEF NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-5832
<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: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<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>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-5832-2	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/27/2019	
2	NDC:11822-5832-3	2 in 1 PACKAGE	12/27/2019	
2		355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:11822-5832-1	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/27/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/27/2019	

**Labeler** - Rite Aid Corporation (014578892)