

**LEADER NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate solution**  
**Cardinal Health 110, LLC. dba Leader**

-----  
**Cardinal Health Nighttime Cold & Flu 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 or comments?

1-800-719-9260

## Package/Label Principal Display Panel

Maximum Strength

Nighttime Cold & Flu

Acetaminophen | Dextromethorphan HBr

Doxylamine Succinate

Pain Reliever / Fever Reducer

Cough Suppressant

Antihistamine

Cherry Flavor

Relief of:

Aches, Fever, Cough  
Sore Throat, Sneezing  
Runny Nose

COMPARE TO VICKS® NYQUIL® COLD & FLU active ingredients

100% Money Back Guarantee

ALCOHOL 10%

8 FL OZ (237 mL)

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

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

© 2016 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

**CardinalHealth™**  
DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myLeader.com 1-800-200-6316  
Essential to Care™ since 1979

**ALL LEADER™ Brand Products Have A 100% Money Back Guarantee**  
Return to place of purchase if not satisfied.

**PARENTS:**  
Learn about teen medicine abuse  
www.StopMedicineAbuse.org

**LEADER™**

NDC 70000-0183-2  
**Maximum Strength**  
**Nighttime Cold & Flu**  
Acetaminophen | Dextromethorphan HBr  
Doxylamine Succinate  
Pain Reliever / Fever Reducer  
Cough Suppressant  
Antihistamine

**Cherry Flavor**  
Relief of :  
Aches, Fever, Cough  
Sore Throat, Sneezing  
Runny Nose

**COMPARE TO VICKS® NYQUIL® COLD & FLU active ingredients\***

**100% Money Back Guarantee**

**8 FL OZ (237 mL)**

Drug Facts	Purpose
<b>Active ingredients (in each 30 mL)</b>	
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  
 ■ minor aches and pains ■ headache ■ fever  
 ■ runny nose and sneezing ■ sore throat

**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.

PEEL BACK AT CORNER FOR MORE INFORMATION →

**Drug Facts (continued)**

**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

**Drug Facts (continued)**

**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.

<b>Directions</b>	
■ 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 or comments? 1-800-719-9260**

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0183
<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>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	

### Product Characteristics

<b>Color</b>	RED (Clear/Dark Red)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (Menthol Aroma)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0183-2	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2016	
2	NDC:70000-0183-1	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2016	03/31/2022

### Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	11/16/2016	

**Labeler** - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 10/2024

Cardinal Health 110, LLC. dba Leader