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

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**Leader 44-013**

### *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 and flu symptoms:
  - headache
  - minor aches and pains
  - sore throat
  - runny nose and sneezing
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever

### *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**

- difficulty in urination due to enlargement of the prostate gland
- liver disease
- glaucoma
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

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

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

**When using this product**

- marked drowsiness may occur
- excitability may occur, especially in children
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 7 days
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- 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. Prompt 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**

- do not exceed 4 doses per 24 hours
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years: do not use

### *Other information*

- **each 30 mL contains:** sodium 13 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

### *Inactive ingredients*

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, high fructose corn syrup, polyethylene glycol 400, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sodium saccharin, sucralose

### *Questions or comments?*

**1-800-426-9391**

### *Principal display panel*

**LEADER™**

NDC 70000-0673-1

**Nighttime**
**Cold & Flu**

**Acetaminophen**
Dextromethorphan HBr
Doxylamine Succinate
Pain Reliever / Fever Reducer
Cough Suppressant
Antihistamine

Cherry
Flavor

Relief of:
• Headache
• Fever
• Sore Throat
• Minor Aches & Pains
• Sneezing
• Runny Nose
• Cough

For Ages 12 & Over

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

100% Money
Back Guarantee

**12 FL OZ (355 mL)**

**TAMPER EVIDENT: DO NOT USE IF PRINTED**
**NECK WRAP IS BROKEN OR MISSING**

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

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® NyQuil® Cold & Flu. 50844 ORG032301302

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**Leader 44-013**

## COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:70000-0673 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg in 30 mL |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg in 30 mL |
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 12.5 mg in 30 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **HIGH FRUCTOSE CORN SYRUP** (UNII: XY6UN3QB6S) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| **TRISODIUM CITRATE DIHYDRATE** (UNII: B22547B95K) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | red | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | CHERRY | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70000-0673-1 | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/02/2024 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 08/02/2024 | |

## Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 967626305 | manufacture(70000-0673) , pack(70000-0673) |

Revised: 8/2025 Cardinal Health 110, LLC. DBA Leader