

COLD AND FLU NIGHTTIME RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

L.N.K. International, Inc.

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.

Convenience Valet 44-014

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:
 - runny nose and sneezing
 - fever
 - sore throat
 - headache
 - minor aches and pains
 - 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 mg of acetaminophen in 24 hours
- 3 or more alcoholic drinks every day while using this product
- with other drugs containing acetaminophen

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
- 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
- liver disease
- glaucoma

Ask a doctor or pharmacist before use if you are

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

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- avoid alcoholic beverages
- marked drowsiness may occur
- 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
- 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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**
- mL = milliliter; FL OZ = fluid ounce
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- do not take more than 4 doses per 24 hours
- 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 18 mg
- use by expiration date on package
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

anhydrous citric acid, D&C yellow #10, FD&C green #3, FD&C yellow #6, flavors, glycerin, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sodium saccharin, sucralose

Questions or comments?

1-844-428-2538

Principal display panel

24/7 life

BY 7-ELEVEN™

Multi-Symptom

Cold & Flu

Nighttime Relief

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Doxylamine Succinate/Antihistamine

Headache, Fever, Sore Throat,

Minor Aches & Pains,

Sneezing, Runny Nose, Cough

QUALITY

GUARANTEED

Alcohol Free

compare to the active ingredients in

VICKS® NYQUIL® COLD & FLU

Nighttime Relief*

12 FL OZ (355 mL)

Eucalyptus Mint Flavor

Drug Facts (continued)

- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

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*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® NyQuil® Cold & Flu Nighttime Relief. 50844 ORG031801402

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WWW.7-ELEVEN.COM

Satisfaction Guaranteed 1-800-255-0711



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PEEL HERE FOR MORE DRUG FACTS



Multi-Symptom
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Nighttime Relief

Acetaminophen
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Nighttime Relief*

12 FL OZ (355 mL) Eucalyptus Mint Flavor

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

Drug Facts

| Active ingredients (in each 30 mL) | Purpose |
|---------------------------------------|-----------------------------|
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Questions or comments? 1-844-428-2538

Convenience Valet 44-014

COLD AND FLU NIGHTTIME RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50844-252 |
| 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) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| 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 | GREEN | Score | |
| Shape | | Size | |
| Flavor | MINT (Eucalyptus Mint) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50844-252-02 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/14/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part341 | 07/14/2019 | |

Labeler - L.N.K. International, Inc. (038154464)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|--|
| LNK International, Inc. | | 967626305 | MANUFACTURE(50844-252) , PACK(50844-252) |

Revised: 6/2019

L.N.K. International, Inc.