COLD AND FLU RELIEF MULTI-SYMPTOM- acetaminophen, dextromethorphan hbr, doxylamine succinate solution
L.N.K. International, Inc.

Quality Plus 44-014-Delisted

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

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 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
- 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, 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?

1-800-426-9391

Principal display panel

QUALITY
+PLUS

NDC 50844-014-45

Compare to active ingredients
in Vicks® NyQuil® Cold & Flu
Nighttime Relief*

Multi-Symptom
COLD & FLU RELIEF

Acetaminophen,
Dextromethorphan HBr,
Doxylamine succinate

PAIN RELIEVER/FEVER REDUCER
COUGH SUPPRESSANT
ANTIHISTAMINE

NIGHTTIME

Alcohol Free

Eucalyptus Mint

Flavor

6 FL OZ (177 mL)

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

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® NyQuil® Cold & Flu Nighttime Relief. 50844 REV0318A01445

Distributed by **LNK INTERNATIONAL, INC.**
60 Arkay Drive
Hauppauge, NY 11788
USA

Quality Plus 44-014

COLD AND FLU RELIEF MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-014
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: 3WQ0SDW1A)	
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)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-014-45	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/10/2019	11/30/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/10/2019	11/30/2024

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(50844-014) , pack(50844-014)

Revised: 7/2024

L.N.K. International, Inc.