COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, phenylephrine hcl solution L.N.K. International, Inc.

Quality Plus 44-012

Active ingredients (in each 15 mL)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer Cough suppressant Nasal decongestant

Uses

- temporarily relieves common cold and flu symptoms:
 - sore throat
 - nasal congestion
 - fever
 - 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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product
- child takes more than 5 doses in 24 hours

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 the user has

- thyroid disease
- difficulty in urination due to enlargement of the prostate gland
- heart disease
- liver disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- high blood pressure

Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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 5 doses per 24 hours

adults and children 12 years and	30 mL every 4
over	hours
Children 6 to tinger 17 years	15 mL every 4
	hours
children under 6 years	do not use

Other information

- each 15 mL contains: sodium 13 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, FD&C yellow #6, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sodium saccharin, sorbitol, sucralose

Questions or comments?

1-800-426-9391

Principal display panel

QUALITY +PLUS

NDC 50844-120-45

Compare to active ingredients in Vicks® DayQuil® Cold & Flu Multi-Symptom Relief*

Multi-Symptom

COLD & FLU RELIEF

Acetaminophen,

Dextromethorphan HBr, Phenylephrine HCl

PAIN RELIEVER/FEVER REDUCER COUGH SUPPRESSANT NASAL DECONGESTANT

DAYTIME

Non-Drowsy Alcohol Free

Menthol Flavor

6 FL OZ (177 mL)

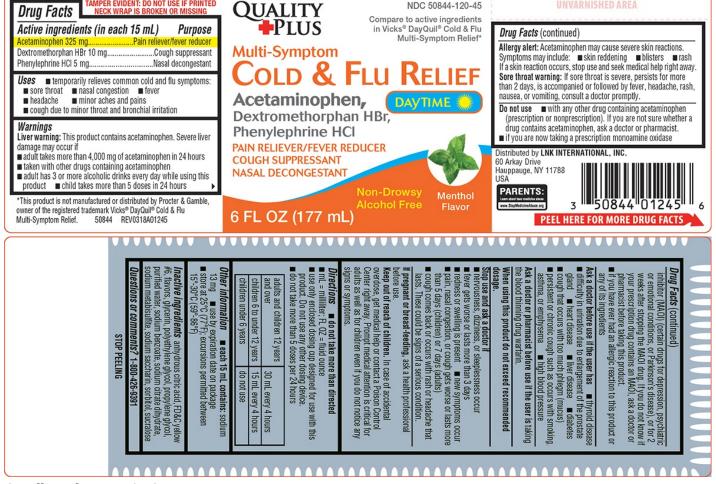
TAMPER EVIDENT: DO NOT USE IF PRINTED NECK WRAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil® Cold & Flu Multi-Symptom Relief. 50844 REV0318A01245

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

PARENTS:

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Quality Plus 44-012

COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50844-120

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
SODIUM METABISULFITE (UNII: 4VON5FNS3C)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UO3ZD4)		

Product Characteristics			
Color	orange	Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50844-120-45	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/28/2022	

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

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

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		967626305	manufacture(50844-120) , pack(50844-120)	

Revised: 5/2023 L.N.K. International, Inc.