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

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#### 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
	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<sup>®</sup> DayQuil<sup>®</sup> 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  $^{\mbox{\scriptsize B}}$  DayQuil  $^{\mbox{\scriptsize B}}$  Cold & Flu Multi-Symptom Relief.

50844 REV0318A01245

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

#### **PARENTS:**

Learn about teen medicine abuse www.StopMedicineAbuse.org



Quality Plus 44-012

# COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

<b>Product Info</b>	ormation								
Product Type		HUMAN OTC DRUG	ltem Code	(Source)	NDC:508	344-120			
Route of Admin	nistration	ORAL							
Noute of Admin									
Active Ingred	Active Ingredient/Active Moiety								
Ingredient Name Basis of Stren				ngth	Strength				
ACETAMINOPHEI	TAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN					325 mg in 15 mL			
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) DEXTROMETHORPHAN (DEXTROMETHORPHAN - UNII:7355X3ROTS) DEXTROMETHORPHAN				IAN	10 mg in 15 mL				
PHENYLEPHRINE	PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - PHENYLEPHRINE				5 mg in 15 mL				
	,								
Inactive Ingr	edients								
Ingredient Name					S	strength			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)									
FD&C YELLOW N	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)								
GLYCERIN (UNII: F	PDC6A3C0OX)								
POLYETHYLENE	GLYCOL, UNSPI	ECIFIED (UNII: 3WJQ0SDW14	4)						
PROPYLENE GLY	COL (UNII: 6DC9	Q167V3)							
WATER (UNII: 059	QF0KO0R)								
SODIUM BENZOA	<b>ATE</b> (UNII: 0J2451	FE5EU)							
TRISODIUM CITR	ATE DIHYDRAT	<b>E</b> (UNII: B22547B95K)							
SODIUM METABI	SULFITE (UNII: 4	IVON5FNS3C)							
SACCHARIN SOD	IUM (UNII: SB8Z	UX40TY)							
SORBITOL (UNII:	506T60A25R)								
SUCRALOSE (UNI	I: 96K6UQ3ZD4)								
Broduct Cha	ractorictica								
Product Characteristics		prange	Score						
Shape	U	ange	Size						
Flavor	N	IENTHOL							
Contains	1.	MENTHOL Imprint Code							
Contains									
Packaging									
# Item Code			-		eting End Date				
NDC:50844-	177 mL in 1 BO	TTLE, PLASTIC; Type 0: Not	a			Date			
<b>1</b> 120-45			4/28/2022						

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	04/28/2022			

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: 5/2024

L.N.K. International, Inc.