

COLD AND FLU RELIEF DAYTIME, MULTI-SYMPTOM- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled
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.

Quality Plus 44-659

Active ingredients
(in each liquid-filled capsule)

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
 - headache
 - fever
 - 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 in 24 hours, which is the maximum daily amount
- 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

- 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
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

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
- pain, nasal congestion, 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
- persistent cough lasts for more than one week, tends to recur, or is accompanied by fever, rash, or persistent headache

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**
- do not take more than 8 capsules per 24 hours
- adults and children 12 years and over: take 2 capsules with water every 4 hours
- children under 12 years: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

- protect from heat, humidity and light
- see end flap for expiration date and lot number

Inactive ingredients

edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin, mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol

Questions or comments?

1-800-426-9391

Principal Display Panel

QUALITY

+ PLUS

NDC 50844-659-21

*Compare to active ingredients in Vicks® DayQuil® Cold & Flu LiquiCaps®

DAYTIME

MULTI-SYMPTOM

COLD &

FLU RELIEF

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl

PAIN RELIEVER/FEVER REDUCER,

COUGH SUPPRESSANT, NASAL DECONGESTANT

- Headache
- Cough
- Fever
- Antihistamine-Free
- Sore Throat
- Nasal Congestion
- Alcohol-Free

16 Liquid Caps NON-DROWSY

ACTUAL SIZE

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil® Cold & Flu LiquiCaps®.

50844 ORG021665921

Product of China

Packaged and Quality Assured in the USA

Distributed by

LNK INTERNATIONAL, INC

60 Arkay Drive

Hauppauge, NY 11788

USA

Drug Facts (continued)

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COUGH SUPPRESSANT, PAIN RELIEVER/FEVER REDUCER,

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COLD & FLU RELIEF

DAYTIME

MULTI-SYMPOM

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NDC 50844-659-21



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No print/No varnish Lot & Exp date



Distributed by
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60 Arkay Drive
Hauppauge, NY 11788
USA

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B-1603-659-21-R
ORG021665921

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredients (in each liquid-filled capsule)

| Active ingredients | Purpose |
|----------------------------|-----------------------------|
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Drug Facts (continued)

■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

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Quality Plus 44-659

COLD AND FLU RELIEF DAYTIME, MULTI-SYMP TOM

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50844-659 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------------|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------------------------|----------|
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| GELATIN (UNII: 2G86QN327L) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | ORANGE | Score | no score |
| Shape | OVAL | Size | 21mm |
| Flavor | | Imprint Code | 659 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:50844-659-21 | 2 in 1 CARTON | 03/01/2015 | |
| 1 | | 8 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part341 | 03/01/2015 | |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------------------------------|---------|-----------|----------------------------|
| Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd | | 421293287 | API MANUFACTURE(50844-659) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 967626305 | PACK(50844-659) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 832867837 | PACK(50844-659) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 868734088 | PACK(50844-659) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 038154464 | PACK(50844-659) |

Revised: 9/2019

L.N.K. International, Inc.