

SINUS AND CONGESTION RELIEF DAYTIME- acetaminophen, 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 44-663

Active ingredients (in each liquid-filled capsule)

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
 - sinus congestion and pressure
 - fever
 - nasal congestion
 - headache
 - minor aches and pains

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:

- blisters
- rash
- skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

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 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

- liver disease
- diabetes
- heart disease
- thyroid disease
- high blood pressure
- 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

- redness or swelling is present
- new symptoms occur
- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days

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

- **take only as directed**
- do not exceed 4 doses per 24 hours
- adults and children 12 years and over: 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)
- see end flap for expiration date and lot number

Inactive ingredients

edible white ink, 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 50844-663-02

Compare to active ingredients in Vicks® QlearQuil™ Daytime Sinus & Congestion

Sinus & Congestion Relief

DAYTIME

Acetaminophen

Phenylephrine HCl

PAIN RELIEVER / FEVER REDUCER

NASAL DECONGESTANT

- Nasal and Sinus Congestion
- Fever
- Sinus Headache and Pain
- Pseudoephedrine Free

ACTUAL SIZE

12 Liquid Caps

NON-DROWSY

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

Distributed by

LNK INTERNATIONAL, INC.

60 Arkay Drive, Hauppauge, NY 11788

USA

*This product is not manufactured or distributed by
Procter & Gamble, owner of the registered trademark
Vicks® QlearQuil™ Daytime Sinus & Congestion.

50844 ORG061666302


Product of China

Packaged and Quality Assured in the USA

<p>Drug Facts (continued)</p> <p>■ difficulty in urination due to enlargement of the prostate gland</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <p>When using this product do not exceed recommended dosage.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ redness or swelling is present ■ new symptoms occur ■ nervousness, dizziness, or sleepiness occur ■ pain or nasal congestion gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days <p>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.</p> <p>Directions ■ take only as directed</p> <ul style="list-style-type: none"> ■ do not exceed 4 doses per 24 hours ■ adults and children 12 years and over: 2 capsules with water every 4 hours ■ children under 12 years: ask a doctor <p>Other information</p> <ul style="list-style-type: none"> ■ 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) ■ see end flap for expiration date and lot number <p>Inactive ingredients edible white ink, FD&C yellow #6, gelatin, glycerin, lecithin, mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol</p> <p>Questions or comments? 1-800-426-9391</p>	<p>Drug Facts</p> <p>Keep Outer Package For COMPLETE PRODUCT INFORMATION</p> <p>Active ingredients (in each liquid-filled capsule)</p> <p>Acetaminophen 325 mg Pain reliever/fever reducer</p> <p>Phenylephrine HCl 5 mg Nasal decongestant</p> <p>Uses ■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: ■ sinus congestion and pressure ■ fever</p> <p>■ temporarily relieves the symptoms associated with hay fever or other upper respiratory allergies, and the common cold: ■ sinus congestion and pressure ■ fever ■ nasal congestion ■ headache ■ minor aches and pains</p> <p>Warnings 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</p> <p>■ 3 or more alcoholic drinks every day while using this product</p> <p>Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ blisters ■ rash ■ skin redness</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ with any other drug containing acetaminophen (prescription or nonprescription), ask a doctor or pharmacist ■ if you are now taking a prescription monoamine oxidase inhibitor or 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 <p>Ask a doctor before use if you have ■ liver disease ■ diabetes ■ heart disease ■ thyroid disease ■ high blood pressure</p>
---	---

QUALITY PLUS Sinus & Congestion Relief **DAYTIME**

B-1603-663-02
ORG061666302



NDC 50844-663-02

Compare to active ingredients in Vicks® ClearQuil™ Daytime Sinus & Congestion

Sinus & Congestion Relief

Acetaminophen Phenylephrine HCl


DAYTIME

PAIN RELIEVER / FEVER REDUCER NASAL DECONGESTANT

- Nasal and Sinus Congestion
- Fever
- Sinus Headache and Pain
- Pseudoephedrine Free

12 Liquid Caps

NON-DROWSY



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

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

No Print / No Varnish Lot no. & Exp. date



*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® ClearQuil™ Daytime Sinus & Congestion.
50844 ORG061666302
Product of China
Packaged and Quality Assured in the USA

Quality Plus 44-663

SINUS AND CONGESTION RELIEF DAYTIME

acetaminophen, phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50844-663
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

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

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	663
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-663-02	1 in 1 CARTON	03/01/2015	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50844-663-00	2 in 1 CARTON	03/01/2015	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50844-663-08	3 in 1 CARTON	03/01/2015	
3		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(50844-663)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(50844-663)

Revised: 7/2019

L.N.K. International, Inc.