# COLD AND FLU RELIEF NIGHTTIME, MULTI-SYMPTOM- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled ARMY AND AIR FORCE EXCHANGE SERVICE

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.

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#### Exchange Select 44-660

## Active ingredients (in each liquid-filled capsule)

Acetaminophen 325 mg Dextromethorphan HBr 15 mg Doxylamine succinate 6.25 mg

#### **Purpose**

Pain reliever/fever reducer Cough suppressant Antihistamine

#### Uses

- temporarily relieves common cold and flu symptoms:
  - sore throat
  - minor aches and pains
  - fever
  - headache
  - runny nose and sneezing
  - 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
- 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
- to make a child sleepy
- 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
- glaucoma
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- 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
- taking sedatives or tranquilizers

#### When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- avoid alcoholic beverages
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

#### 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 (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 6 hours
- children under 12 years: ask a doctor

- protect from heat, humidity and light
- 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**

D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol

#### Questions or comments?

1-800-426-9391

#### **Principal Display Panel**

exchange [select<sub>TM</sub>

Compare to the Active Ingredients of Vicks® NyQuil® Cold & Flu LiquiCaps® \*

NightTime Cold & Flu Relief MULTI-SYMPTOM

#### Acetaminophen,

Dextromethorphan HBr, Doxylamine succinate

- Pain Reliever/Fever Reducer
- Cough Suppressant
- Antihistamine

**Actual Size** 

#### 24 Liquid Caps

quality value

## 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<sup>®</sup> NyQuil<sup>®</sup> Cold & Flu LiquiCaps<sup>®</sup>.

#### **Product of China**

Packaged and Quality Assured in the USA

#### "SATISFACTION GUARANTEED OR YOUR MONEY BACK"

Manufactured For your Military Exchanges Distributed by: LNK International, Inc. Hauppauge, NY 11788 1-800-426-9391

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# **NightTime**

Cold & Flu Relief MULTI-SYMPTOM

> Compare To The Active Ingredients of Vicks® NyQuil® Cold & Flu LiquiCaps®\*

exchange select

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

ot no. & Exp. date

No print area

# NightTime

## Cold & Flu Relief

### **MULTI-SYMPTOM** Acetaminophen,

Dextromethorphan HBr, Doxylamine succinate



24 Liquid Caps

 Pain Reliever/Fever Reducer Cough Suppressant Antihistamine

quality

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REV0418D66008

"SATISFACTION GUARANTEED OR YOUR MONEY BACK"
Manufactured for Your Military Exchanges
Distributed by: LINK International, Inc.
Hauppauge, NY 1788
1-800-426-9391

value

OTHER INFORMSTION Protect from heat, humidify and light

TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED

OR BLISTER IS TORN OR BROKEN

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Drug Facts (continued)

Questions or comments? 1-800-426-9391

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**Drug Facts** (continued)

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Symptoms and seek medical help right away. Allergy alert: Acetaminophen may cause severe skin reactions. 3 or more alcoholic drinks every day while using this product ■ with other drugs containing acetaminophen ■ more than 4,000 mg of acetaminophen in 24 hours

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minor aches and pains 1sore throat USes at temporarily relieves common cold and flu symptoms: Doxylamine succinate 6.25 mg

COMPLETE PRODUCT INFORMATION

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Drug Facts

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Drug Facts (continued)

Purpose

### COLD AND FLU RELIEF NIGHTTIME, MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-660
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg	
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	

Inactive Ingredients			
Ingredient Name	Strength		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
PO VIDO NE (UNII: FZ989 GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			

Product Characteristics			
Color	GREEN (clear)	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	660
Contains			

l	Packaging				
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
	1 NDC:55301-660-08	2 in 1 CARTON	03/01/2015		
l	1	12 in 1 BLISTER PACK; Type 0: Not a Combination Product			

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

## Labeler - ARMY AND AIR FORCE EXCHANGE SERVICE (001695568)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		832867837	PACK(55301-660)	

Revised: 9/2019

ARMY AND AIR FORCE EXCHANGE SERVICE