# VICKS NYQUIL COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled Mechanical Servants, 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.

-----

Vicks<sup>®</sup> NyQuil<sup>®</sup> Cold and Flu

**Drug Facts** 

Active ingredients (in each LiquiCap)	Purpose
Acetaminophen 325 mg	Pain reliever/ fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

#### Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing

#### **Warnings**

#### Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

#### Sore throat warning

If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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.
- to make a child sleep

#### Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland

### Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

#### When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, & tranquilizers may increase drowsiness

#### 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.

#### Overdose warning

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

#### **Directions**

- take only as directed see Overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 LiquiCaps with water every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 vrs	do not use

 when using other DayQuil® or NyQuil products, carefully read each label to insure correct dosing

#### Other information

• store at room temperature

# **Inactive ingredients**

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, titanium dioxide

# Questions?

1-800-362-1683

Manufactured by Procter & Gamble Cincinnati OH 45202

Distributed by Convenience Valet<sup>®</sup> Melrose Park, IL 60160

# PRINCIPAL DISPLAY PANEL - 2 Capsule Pouch Package

**CONVENIENCE** 

 $\mathbf{CV}$ 

**VALET**®

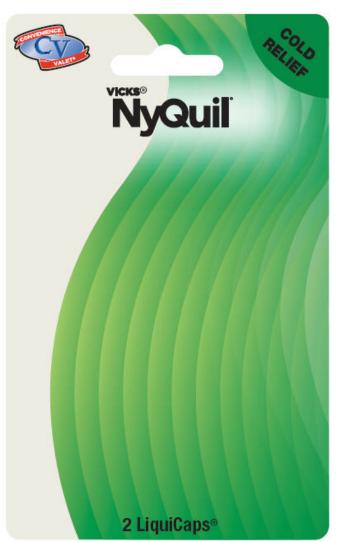
COLD

**RELIEF** 

**VICKS®** 

NyQuil®

2 LiquiCaps®

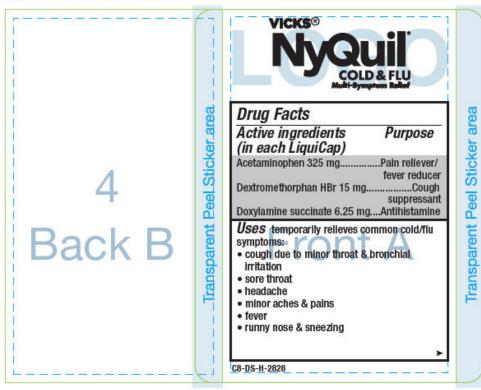


Drug Facts (continued)

Liver warning. This product contains

Warnings





Drug Facts (continued)

MAOI drug. If you do not know if your

prescription drug contains an MAOI, ask

acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- · with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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

a doctor or pharmacist before taking this product. • to make a child sleep

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are • taking sedatives or tranquilizers • taking the blood thinning drug warfarin

#### When using this product

- · do not use more than directed
- excitability may occur, especially in children
- · marked drowsiness may occur
- · avoid alcoholic drinks
- · be careful when driving a motor vehicle

Drug Facts (continued)
or operating machinery
• alcohol, sedatives, & tranquilizers may increase drowsiness
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.

Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

#### Directions

- · take only as directed see Overdose warning
- do not exceed 4 doses per 24 hrs

Drug Facts (continued) 2 LiquiCaps adults & children with water every 6 hrs 12 yrs & over children 4 to ask a doctor under 12 yrs children do not use under 4 yrs when using other DayQuil® or NyQuil products, carefully read each label to insure correct dosing Other information • store at room temperature Inactive ingredients D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, titanium dioxide Questions? 1-800-362-1683 www.vicks.com Manufactured by Procter & Gamble Distributed by Convenience Vale Melrose Park, IL 60160 Cincinnati OH 45202 Made in Canada

# VICKS NYQUIL COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-2828(NDC:37000-557)
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>DEXTRO METHO RPHAN HYDRO BRO MIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DO XYLAMINE SUCCINATE (UNII: V9 BI9 B5 YI2) (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: PDC6 A3C0 OX)			
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
PO VIDO NE (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics			
Color	GREEN	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	NQUIL
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:29485-2828-5	1 in 1 PACKAGE		
1	2 in 1 POUCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 1/0 1/20 10	

# **Labeler** - Mechanical Servants, Inc. (005530951)

Establishment			
Name	Address	ID/FEI	Business Operations
Mechanical Servants, Inc.		005530951	RELABEL

Revised: 1/2012 Mechanical Servants, Inc.