

**VICKS NYQUIL COLD AND FLU NIGHTTIME RELIEF- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate solution**

**The Procter & Gamble Manufacturing Company**

*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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**VICKS®**

**NyQuil®**

**COLD & FLU**

***Drug Facts***

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<b><i>Active ingredients (in each 30 mL dose cup)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine

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**Uses**

temporarily relieves common cold/flu symptoms:

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

**Warnings**

**Liver warning**

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

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day 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
- a sodium-restricted diet

**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, and 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 the recommended dose 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 as well as for children even if you do not notice any signs or symptoms.

**Directions**

- take only as directed - see Overdose warning
- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL (2 TBSP) every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

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

## **dosing**

### **Other information**

- **each 30 mL dose cup contains:** sodium 43 mg
- store at room temperature

### **Inactive ingredients**

alcohol, citric acid, D&C Yellow No. 10, FD&C Green No. 3, FD&C Yellow No. 6, flavor, high fructose corn syrup, PEG-40 stearate, polyethylene glycol, povidone, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, xanthan gum

### **Questions?**

**1-800-362-1683**

**Dist. by**

**Procter & Gamble,  
Cincinnati OH 45202.**

### **PRINCIPAL DISPLAY PANEL - 236 ml Bottle Label**

**VICKS®**

**NyQuil®**

**COLD & FLU**

**Nighttime Relief**

*Acetaminophen, Doxylamine, Dextromethorphan*

- **Aches, Fever & Sore Throat**
- **Sneezing, Runny Nose**
- **Cough**

*Alcohol 10%*

**8 FL OZ (236 ml)**



### PARENTS:

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

**TAMPER EVIDENT:**  
Do not use if printed shrinkband is missing or broken.

QUIET ZONE 4  
P&G  
80% GTIN  
VERSION A  
AREA GAUGE  
23900 01424 4  
3  
QUIET ZONE

Dist. by Procter & Gamble,  
Cincinnati OH 45202.

[www.vicks.com](http://www.vicks.com) 99820281



# NyQuil

## COLD & FLU

### Nighttime Relief

Acetaminophen, Doxylamine, Dextromethorphan

- ♥ Aches, Fever & Sore Throat
- ♥ Sneezing, Runny Nose
- ♥ Cough

Alcohol 10%

8 FL OZ (236 ml)

Failure to follow these warnings could result in serious consequences.

#### Drug Facts

**Active ingredients** Purpose  
(in each 30 mL dose cup)

Acetaminophen 650 mg, . . . . . Pain reliever/fever reducer  
Dextromethorphan HBr 30 mg, . . . . . Cough suppressant  
Doxylamine succinate 12.5 mg, . . . . . Antihistamine

**Uses** temporarily relieves common cold/flu symptoms:

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

#### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take  
• more than 4 doses in 24 hours, which is the maximum daily amount for this product  
• with other drugs containing acetaminophen  
• 3 or more alcoholic drinks every day 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. ▶

PEEL BACK FOR DRUG FACTS



# NyQuil

## COLD & FLU

#### Drug Facts (continued)

- 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
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- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
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#### Ask a doctor or pharmacist before use if you are

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- taking the blood thinning drug warfarin

#### When using this product

- do not use more than directed
- excitability may occur, especially in children

#### Drug Facts (continued)

**If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of children.** **Overdose warning:** Taking more than the recommended dose 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 as well as for children even if you do not notice any signs or symptoms.

#### Directions

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adults & children 12 yrs & over	30 mL (2 TBSP) every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

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

#### Other information

- each 30 mL dose cup contains: potassium 5 mg, sodium 37 mg

- marked drowsiness may occur
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and 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.

- store at room temperature

**Inactive ingredients** acetaminophen potassium, alcohol, citric acid, D&C Yellow No. 10, FD&C Green No. 3, FD&C Yellow No. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

**Questions? 1-800-362-1683**

## VICKS NYQUIL COLD AND FLU NIGHTTIME RELIEF

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37000-807
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ANISE, MENTHOL	<b>Imprint Code</b>	

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-807-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2010	
2	NDC:37000-807-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2010	
3	NDC:37000-807-24	2 in 1 PACKAGE, COMBINATION	06/01/2010	
3	NDC:37000-807-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:37000-807-36	3 in 1 PACKAGE, COMBINATION	06/01/2010	
4	NDC:37000-807-12	354 mL in 1 BOTTLE, PLASTIC; 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	06/01/2010	

**Labeler** - The Procter & Gamble Manufacturing Company (004238200)

Revised: 8/2019

The Procter &amp; Gamble Manufacturing Company