# VICKS NYQUIL HBP COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate liquid

# 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 <sup>®</sup> NyQuil <sup>®</sup> HBP COLD & FLU

## **Drug Facts**

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

**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, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, consult 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.

# 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

- 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

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
- •use dose cup provided
- •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

#### Other information

- each 30 mL contains: potassium 5 mg, sodium 38 mg
- store at room temperature and do not refrigerate

# **Inactive ingredients**

acesulfame potassium, alcohol, citric acid, FD&C Blue No. 1, FD&C Red No. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions?

1-800-362-1683

Dist. by Procter & Gamble, Cincinnati OH 45202.

#### PRINCIPAL DISPLAY PANEL - 354 ml Bottle Label

**NEW** 

**VICKS**®

NyQuil<sup>®</sup>

**HBP** 

COLD & FLU

Acetaminophen: Headache, Fever, Sore Throat,

MinorAches&Pains

Doxylaminesuccinate:Sneezing,RunnyNose

DextromethorphanHBr:Cough

# DECONGESTANT FREE FOR PEOPLE WITH HIGH BLOOD PRESSURE

Cherry Flavor Nighttime Relief Alcohol 10%

12 FL OZ (354 ml)



# VICKS NYQUIL HBP COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-015
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	650 mg in 30 mL
<b>DEXTRO METHO RPHAN HYDRO BRO MIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)		

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:37000-015- 12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 2/0 1/20 17	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 2/0 1/20 17	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

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