VICKS NYQUIL SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride 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.

Vicks ® NyQuil ®

Severe Cold & Flu

Drug Facts

Active ingredients (in each 30 mL dose cup)	***Purpose***
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

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, persists for more than 2 days, is accompanied or 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.
- to make a child sleep

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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
- you get nervous, dizzy or sleepless
- pain, nasal congestion, 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 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 4 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 ensure correct dosing**

Other information

- **each 30 mL dose cup contains:** sodium 92 mg
- store at room temperature

Inactive ingredients

citric acid, FD&C Blue No.1, FD&C Red No. 40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

Questions?

1-800-362-1683

Dist. by
Procter & Gamble,
Cincinnati OH 45202

PRINCIPAL DISPLAY PANEL - 354 mL Bottle Label

NEW
Fights More
Symptoms
than NyQuil
Cold & Flu

VICKS ®

NyQuil ®
SEVERE

COLD & FLU

Nighttime Relief
Acetaminophen, *Phenylephrine HCI, Doxylamine Succinate, Dextromethorphan HBr*

MAX
STRENGTH

- **Headache, Fever, Sore Throat,**
  Minor Aches & Pains
- **Nasal/Sinus Congestion & Sinus Pressure**
- **Sneezing, Runny Nose**
- **Cough**

Berry Flavor

12 FL OZ (354 ml)

TAMPER EVIDENT: Do not use if printed shrinkband is missing or broken. Failure to follow these warnings could result in serious consequences.

PARENTS:
Learn about teen medicine abuse

Drug Facts

www.StopMedicineAbuse.org

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• nasal congestion • sinus congestion & pressure • cough due to minor throat & bronchial irritation • cough to help you sleep • minor aches & pains • headache • fever • sore throat • runny nose & sneezing • reduces swelling of nasal passages • temporarily restores freer breathing through the nose • promotes nasal and/or sinus drainage

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Drug Facts (continued)

FPC

Dist. by 92400410
Procter & Gamble,
Cincinnati OH 45202

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

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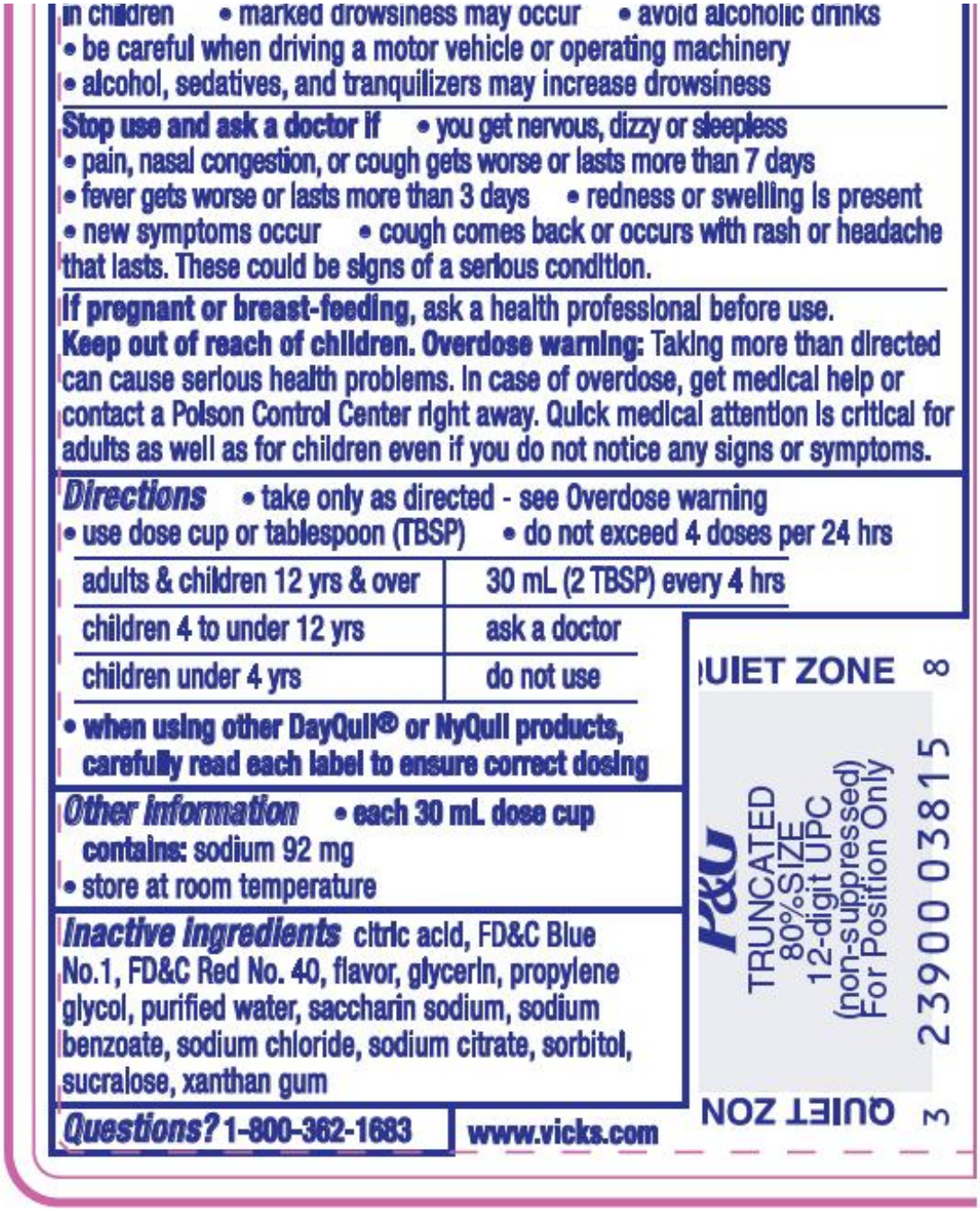

VICKS NYQUIL SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37000-812
Route of Administration	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	20 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-812-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2013	
2	NDC:37000-812-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/2013	
3	NDC:37000-812-24	2 in 1 PACKAGE	07/22/2013	
3		354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:37000-812-36	3 in 1 PACKAGE	07/22/2013	07/10/2019
4		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	07/22/2013	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 2/2021 The Procter & Gamble Manufacturing Company