# VICKS NYQUIL SEVERE HONEY COLD AND FLU- acetaminophen, dextromethrophan, doxylamine succinate, phenylephrine hcl liquid Procter & Gamble Manufacturing Company

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## Vicks NyQuil SEVERE HONEY COLD & FLU Drug Facts

#### Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

#### **Purpose**

Pain reliever/fever reducer Cough suppressant

**Antihistamine** 

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

• adult takes more than 4 doses (30 mL each) in 24 hours, which is the maximum daily

- amount for this product
- child takes more than 4 doses (15 mL each) in 24 hours, which is the maximum daily amount for this product
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks daily 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

- 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 sleepy

## 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

## 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 5 days (children) 7 days (adults)
- 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 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
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	do not use unless directed by a doctor
children under 4 yrs	do not use

#### Other information

- each 15 mL contains: sodium 14 mg
- Store at no greater than 25° C and do not refrigerate.

#### Inactive ingredients

citric acid, D&C Yellow No. 10, FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Questions?

1-800-362-1683

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

Made in Canada

**DIST. BY PROCTER & GAMBLE, CINCINNATI, OH 45202** 

PRINCIPAL DISPLAY PANEL - 354 mL Bottle Label

**VICKS**®

**NyQuil SEVERE™** 

**HONEY** 

COLD & FLU

Acetaminophen, Phenylephrine HCl, Doxylamine Succinate, Dextromethorphan HBr

Headache, Fever, Sore Throat, Minor Aches & Pains

Nasal Congestion, Sinus Pressure

Sneezing, Runny Nose

Cough

Nighttime Relief

12 FL OZ (354 ml)









#### **VICKS NYQUIL SEVERE HONEY COLD AND FLU**

acetaminophen, dextromethrophan, doxylamine succinate, phenylephrine hcl liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69423-968	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL		

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SORBITOL (UNII: 506T60A25R)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics				
Color	brown	Score		
Shape		Size		
Flavor	HONEY	Imprint Code		
Contains				

Packaging				
# Item C	ode	Package Description	Marketing Start Date	Marketing End Date
1 NDC:694 968-12		4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a mbination Product	07/07/2021	
2 NDC:694 968-08		6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a mbination Product	07/07/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/07/2021	

## Labeler - Procter & Gamble Manufacturing Company (004238200)

Establishment				
Name	Address	ID/FEI	Business Operations	
The Procter & Gamble Manufacturing Company		003237963	manufacture(69423-968) , pack(69423-968) , label(69423-968)	

Revised: 10/2023 Procter & Gamble Manufacturing Company