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

Vicks NyQuil D Severe

Cold & Flu

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 1000 mg
Dextromethorphan HBr 30 mg
Doxylamine succinate 12.5 mg
Pseudoephedrine HCl 60 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. The maximum daily amount for this product is 3 doses (3,000 mg acetaminophen) in 24 hours.

Severe liver damage may occur if you take:

- more than 4 doses (4,000 mg acetaminophen) in 24 hours
- 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, 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.

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to enlarged prostate gland
- 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

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

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
- only use the dose cup provided
- do not exceed 3 doses per 24 hrs

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

Other information

- **each 30 mL dose cup contains:** sodium 39 mg
- store at 20°-25°C (68°-77°F) and do not refrigerate

Inactive ingredients

alcohol, anhydrous 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 - 355 mL Bottle Label

MAX
STRENGTH

VICKS®

NyQuil™♦D

SEVERE

Cold & Flu

Acetaminophen, Pseudoephedrine HCl, Doxylamine succinate, Dextromethorphan HBr,

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

- **Sneezing, Runny Nose**
- **Cough**

Nighttime Relief

Alcohol 10%

12 FL OZ
(355 ml)

VICKS NYQUIL D SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and pseudoephedrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37000-920
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 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
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

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:37000-920-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/17/2018	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 12/2018 The Procter & Gamble Manufacturing Company