

NYQUIL SEVERE PLUS VICKS VAPOCOOL- 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.

NyQuil™ Severe +

Vicks ® VapoCool™

Cold & Flu

Drug Facts

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Doxylamine succinate 12.5 mg
Phenylephrine HCl 10 mg

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 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, 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

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 4 doses per 24 hrs

adults & children 12 yrs & over 30 mL every 4 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 81 mg
- do not exceed 25°C. Do not refrigerate.

Inactive ingredients

alcohol, citric acid, D&C Yellow No. 10, FD&C Blue No. 1, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose

Questions?

1-800-362-1683

DIST. BY PROCTER & GAMBLE,
CINCINNATI OH 45202

PRINCIPAL DISPLAY PANEL - 354mL Bottle Label

NyQuil™

SEVERE +

VICKS® VapoCOOL™

COLD & FLU

Acetaminophen, Phenylephrine HCl,
Doxylamine Succinate, Dextromethorphan HBr

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

Alcohol 10%

12 FL OZ (354 ml)

Drug Facts (continued)

- 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
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Dist. by Procter & Gamble, Cincinnati OH 45202
 Patents: www.pg.com/patents
 Questions? 1-800-362-1683
 91718406
 www.vicks.com

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

PARENTS: Learn about tamper evidence at www.ShopWithConfidence.com

Drug Facts

Active ingredients (in each 30 mL)	Purpose
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NYQUIL SEVERE PLUS VICKS VAPOCOOL

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-530
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 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 BLUE NO. 1 (UNII: HBR47K3TBD)	

GLYCERIN (UNII: PDC6A3C00X)	
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)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	ANISE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-530-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/10/2018	07/10/2019
2	NDC:37000-530-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/10/2018	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 7/2019

The Procter & Gamble Manufacturing Company