

**DAYQUIL AND NYQUIL SEVERE PLUS VICKS VAPOCOOL COLD AND FLU-
acetaminophen, phenylephrine hydrochloride, and doxylamine succinate**

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.

DayQuil & Nyquil Severe + Vicks VapoCool Cold & Flu Caplets 48 ct Combo pack

DayQuil SEVERE + Vicks® VapoCool™ Cold & Flu

Active ingredients 9in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/Fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- minor aches & pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 8 caplets 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.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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

When using this product, do not use more than directed.

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. 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
- do not exceed 8 caplets per 24 hrs

adults & children 12 yrs & over 2 caplets with water every 4 hrs

children 4 to under 12 yrs ask a doctor
children under 4 yrs do not use

Other information

each caplet contains:

- sodium 4 mg
- do not exceed 25°C

Inactive ingredients

croscarmellose sodium, crospovidone, FD&C Yellow No. 6 Aluminum Lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions?

1-800-362-1683

NyQuil™ SEVERE + Vicks® VapoCool™ Cold & Flu

Active ingredients (in each caplet)

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 you take

- more than 8 caplets 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

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 & 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. 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
- do not exceed 8 caplets per 24 hrs

adults & children 12 yrs & over 2 caplets with water every 4 hrs
children 4 to under 12 yrs ask a doctor
children under 4 yrs do not use

Other information

- do not exceed 25°C

Inactive ingredients

crospovidone, D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions?

1-800-362-1683

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

PRINCIPAL DISPLAY PANEL - Kit Carton

DayQuil™

SEVERE +

VICKS® VapoCOOL™

COLD & FLU

Acetaminophen, Phenylephrine HCl,

DextromethorphanHBr, Guaifenesin

- Minor Aches & Pains, Fever

- Nasal Congestion & Sinus Pressure
- Cough
- Chest Congestion
-

Non-Drowsy

32 DAYQUIL COATED CAPLETS

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

Nighttime Relief

16 NYQUIL COATED CAPLETS; **48 TOTAL COATED CAPLETS**

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-534
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-534-48	1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	08/01/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	16 BLISTER PACK	32
Part 2	8 BLISTER PACK	16

Part 1 of 2**DAYQUIL SEVERE PLUS VICKS VAPOCOOL COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet

Product Information

Item Code (Source)	NDC:37000-524
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSPVIDONE (UNII: 2S7830E561)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
TALC (UNII: 7SEV7J4R1U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	orange	Score	no score
Shape	BULLET	Size	19mm
Flavor		Imprint Code	DQ
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 BLISTER PACK; 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	08/01/2018	

Part 2 of 2

NYQUIL SEVERE PLUS VICKS VAPOCOOL COLD AND FLU

acetaminophen, phenylephrine hydrochloride, doxylamine succinate, and dextromethorphan hydrobromide tablet, coated

Product Information

Item Code (Source)	NDC:37000-523
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
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FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	green	Score	no score
Shape	BULLET	Size	19mm
Flavor		Imprint Code	NQ
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 BLISTER PACK; 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	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2018	

Labeler - The Procter & Gamble Manufacturing Company (004238200)