#### DAYQUIL AND NYQUIL VAPOCOOL SEVERE COLD AND FLU PLUS CONGESTIONacetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride The Procter & Gamble Manufacturing Company

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VICKS <sup>®</sup> DayQuil<sup>™</sup> NyQuil<sup>™</sup> VapoCOOL<sup>™</sup> SEVERE COLD & FLU + CONGESTION Convenience Pack

Vicks ® NyQuil<sup>™</sup> VapoCOOL<sup>™</sup> SEVERE COLD & FLU + CONGESTION

**Drug Facts** 

#### Active ingredients (in each 30 mL)

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

## 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.

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

#### Other information

- each 30 mL contains: sodium 81 mg
- store at no greater than 25°C and 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

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

**DIST. BY PROCTER & GAMBLE,** 

## **CINCINNATI OH 45202**

## Vicks ® DayQuil<sup>™</sup> VapoCOOL<sup>™</sup> SEVERE COLD & FLU + CONGESTION

**Drug Facts** 

#### Active ingredients (in each 30 mL)

#### Acetaminophen 650 mg

Dextromethorphan HBr 20 mg Guaifenesin 400 mg Phenylephrine HCl 10 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 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.

## 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
- a sodium-restricted diet

## 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,

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#### Directions

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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 contains: sodium 81 mg
- store at no greater than 25°C and 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?

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**DIST. BY PROCTER & GAMBLE,** 

CINCINNATI OH 45202

#### **PRINCIPAL DISPLAY PANEL - Convenience Pack**

MAX STRENGTH COOLING RELIEF DAY & NIGHT PACK VICKS <sup>®</sup> DAYQUIL NYQUIL VICKS <sup>®</sup> DayQuil<sup>™</sup> VapoCOOL<sup>™</sup> SEVERE COLD & FLU + CONGESTION **Acetaminophen,**Guaifenesin, Phenylephrine HCl, Dextromethorphan HBr Headache, Fever, Sore Throat, Minor Aches & Pains Chest Congestion, Thins & Loosens Mucus Nasal Congestion, Sinus Pressure Cough *Non-Drowsy Alcohol 10%* Vicks <sup>®</sup>NyQuil<sup>™</sup> VapoCOOL<sup>™</sup> SEVERE COLD & FLU + CONGESTION *Acetaminophen*, Phenylephrine HCl, Doxylamine Succinate, Dextromethorphan HBr Headache, Fever, Sore Throat, Minor Aches & Pains Nasal Congestion & Sinus Pressure Sneezing, Runny Nose Cough *Nighttime Relief Alcohol 10%* 

2 BOTTLES - 1 DAYQUIL/1 NYQUIL; 12 FL OZ (354 mL) EACH; TOTAL 24 FL OZ (708 mL)



# DAYQUIL AND NYQUIL VAPOCOOL SEVERE COLD AND FLU PLUS CONGESTION

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride kit

Ρ	Product Information						
Product Type			HUMAN OTC DRUG	ltem Code (Source)		NDC:69423-991	
Pa	Packaging						
#		n Code Package Description		n	Marketing Start Date	Marketing End Date	
1	<b>1</b> NDC:69423-991- 24 Produc			PACKAGE; Type 0: Not a Combination		03/22/2021	
Q	Quantity of Parts						
Pa	art #		Package Quantity Total Product Quantity			uantity	
Pa	rt 1	1 BOTTLE,	PLAST	ïC	236 mL		
Ра	rt 2	1 BOTTLE,	PLAST	ïC	236 mL		

# Part 1 of 2

# DAYQUIL VAPOCOOL SEVERE COLD AND FLU PLUS CONGESTION

acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide, and guaifenesin solution

#### **Product Information**

Item Code (Source)	NDC:69423-990
Route of Administration	ORAL

Active Ingredient/Active Moiety					
Ingredient Name	<b>Basis of Strength</b>	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL			
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL			
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 30 mL			
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL			

#### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

# **Product Characteristics**

Color	blue	Score
Shape		Size
Flavor	ANISE	Imprint Code
Contains		

Pa	ackaging				
#	Item Code	Pa	ackage Description	Marketing Start Date	Marketing End Date
1	NDC:69423- 990-08	236 mL in 1 BO Combination Pro	TTLE, PLASTIC; Type 0: Not a oduct		
2	NDC:69423- 990-12	354 mL in 1 BO Combination Pro	TTLE, PLASTIC; Type 0: Not a oduct		
Μ	larketing	Informat	ion		
	Marketing Category	Applica	tion Number or Monograph Citation	Marketing Start Date	Marketing End Date
01	C Monograph D	rug M012	03	8/21/2021	
ad	-	n, dextrometh	SEVERE COLD AND FL orphan hydrobromide, doxylamir		
Ρ	roduct Info	rmation			
Item Code (Source) NDC:69423-989					
R	oute of Admir	nistration	ORAL		
A	ctive Ingred	lient/Active	Moiety		
		Ingred	lient Name	Basis of Stren	igth Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 650 mg in 30 mL					650 mg in 30 mL

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)DEXTROMETHORPHAN20 mg<br/>in 30 mL(DEXTROMETHORPHAN - UNII:7355X3ROTS)DEXTROMETHORPHAN20 mg<br/>in 30 mLDOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE -<br/>UNII:95QB77JKPL)DOXYLAMINE SUCCINATE12.5 mg<br/>in 30 mLPHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -<br/>PHENYLEPHRINEPHENYLEPHRINE10 mg

UNII: 1W5 297W6MV) HYDROCHLORIDE in 30 mL
Inactive Ingredients
Ingredient Name
SUCRALOSE (UNII: 96K6UQ3Z D4)
SORBITOL (UNII: 506T60A25R)

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)FD&C BLUE NO. 1 (UNII: H3R47K3TBD)ALCOHOL (UNII: 3K9958V90M)PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

SACCHARIN SOD					
SODIUM BENZOA					
SODIUM CITRATI					
D&C YELLOW NO					
GLYCERIN (UNII: F					
SODIUM CHLORI	<b>DE</b> (UNII: 451W4	7IQ8X)			
Product Chai	racteristics				
Color		blue	Score		
Shape			Size		
Flavor		ANISE	Imprint Cod	le	
Contains					
Packaging					
# Item Code	Р	ackage Descripti	on	Marketing Start Date	Marketing End Date
<b>1</b> NDC:69423- 989-08		6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a mbination Product			
<b>2</b> NDC:69423- 989-12	354 mL in 1 BO Combination Pr	L in 1 BOTTLE, PLASTIC; Type 0: Not a ination Product			
Marketing	Informat	ion			
Marketing Category	Applica	tion Number or M Citation	onograph	Marketing Start Date	Marketing End Date
OTC Monograph D	rug M012			03/22/2021	
Marketing	Informat	ion			
Marketing	Applica	tion Number or M	onograph	Marketing Start	Marketing End

Marketing<br/>CategoryApplication Number or Monograph<br/>CitationMarketing Start<br/>DateMarketing End<br/>DateOTC Monograph DrugM01203/22/2021

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 10/2023

The Procter & Gamble Manufacturing Company