VICKS DAYQUIL AND VICKS NYQUIL SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and doxylamine succinate

The Procter & Gamble Manufacturing Company

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Vicks <sup>®</sup> DayQuil<sup>™</sup> Severe and Vicks <sup>®</sup> NyQuil Severe Cold and Flu Convenience Pack

DayQuil Severe Cold & Flu

**Drug Facts** 

# Active ingredients (in each 15 mL)

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

- adult takes more than 4 doses (30 mL each) in 24 hrs, which is the maximum daily amount for this product
- child takes more than 4 doses (15 mL each) in 24 hrs, which is the maximum daily amount for this product
- taken with other drugs containing acetaminophen
- adult has 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 5 days (children) or 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 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 & 30 mL every 4 over hrs

children 6 to under 12 yrs

children 4 to under 6 yrs ask a doctor children under 4 yrs

30 mL every 4 hrs

ask a doctor do not use

#### Other information

- each 15 mL tablespoon contains:sodium 47 mg
- store at no greater than 25°C and do not refrigerate.

# Inactive ingredients

citric acid, FD&C Yellow No. 6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

**Questions?** 

1-800-362-1683

NyQuil Severe Cold & Flu

**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 & 30 mL every 4 over 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
- store at no greater than 25°C and do not refrigerate

#### **Inactive ingredients**

alcohol, citric acid, D&C Yellow No. 10, FD&C Yellow No. 6, FD&C Green No. 3, 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

PRINCIPAL DISPLAY PANEL - Convenience Pack

**MAX** 

STRENGTH

**DAY & NIGHT PACK** 

**VICKS**®

DayQuil™ SEVERE

**COLD & FLU** 

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 Free

NyQuil™

#### **SEVERE**

#### **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

#### Alcohol 10%

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



## VICKS DAYQUIL AND VICKS NYQUIL SEVERE COLD AND FLU

**Package Quantity** 

Part #

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

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:37000-045 Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:37000-045-24 1 in 1 PACKAGE 07/31/2014 Quantity of Parts

**Total Product Quantity** 

| Part 1 | 1 BOTTLE, PLASTIC | 354 mL |
|--------|-------------------|--------|
| Part 2 | 1 BOTTLE, PLASTIC | 354 mL |

# Part 1 of 2

# **VICKS DAYQUIL SEVERE COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

#### **Product Information**

Item Code (Source) NDC:37000-810

**Route of Administration** ORAL

| Active Ingredient/Active Moiety  |                                  |                    |  |
|--|----------------------------------|--------------------|--|
| Ingredient Name Basis of Strength St   |                                  |                    |  |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)                           | ACETAMINOPHEN                    | 325 mg<br>in 15 mL |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 10 mg<br>in 15 mL  |  |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                               | GUAIFENESIN                      | 200 mg<br>in 15 mL |  |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)            | PHENYLEPHRINE<br>HYDROCHLORIDE   | 5 mg<br>in 15 mL   |  |

| Inactive Ingredients                       |          |  |  |
|--|----------|--|--|
| Ingredient Name                            | Strength |  |  |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) |          |  |  |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)       |          |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                |          |  |  |
| 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: 96K6UQ3Z D4)              |          |  |  |
| XANTHAN GUM (UNII: TTV12P4NEE)             |          |  |  |

| Product Characteristics |       |              |  |
|-------------------------|-------|--------------|--|
| <b>Color</b> orange     |       | Score        |  |
| Shape                   |       | Size         |  |
| Flavor                  | BERRY | Imprint Code |  |
| Contains                |       |              |  |

| l | Packaging                       |                      |  |                       |  |
|---|---------------------------------|----------------------|--|-----------------------|--|
|   | # Item Code Package Description |                      | Marketing Start<br>Date  | Marketing End<br>Date |  |
|   | 1                               | NDC:37000-<br>810-12 | 354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                       |  |

| Marketing Information   |      |                         |                       |  |
|---|------|-------------------------|-----------------------|--|
| Marketing Application Number or Monograp<br>Category Citation |      | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug  | M012 | 07/22/2013              |                       |  |

# Part 2 of 2

# **VICKS NYQUIL SEVERE COLD AND FLU**

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

| Product Information     |               |  |  |
|-------------------------|---------------|--|--|
| Item Code (Source)      | NDC:37000-815 |  |  |
| Route of Administration | ORAL          |  |  |

| Active Ingredient/Active Moiety  |                                  |                     |  |  |
|--|----------------------------------|---------------------|--|--|
| Ingredient Name  | Basis of Strength                | Strength            |  |  |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)                           | ACETAMINOPHEN                    | 650 mg<br>in 30 mL  |  |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 20 mg<br>in 30 mL   |  |  |
| DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)                       | DOXYLAMINE SUCCINATE             | 12.5 mg<br>in 30 mL |  |  |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)            | PHENYLEPHRINE<br>HYDROCHLORIDE   | 10 mg<br>in 30 mL   |  |  |

| Inactive Ingredients                       |  |  |  |
|--|--|--|--|
| Ingredient Name Strengt                    |  |  |  |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) |  |  |  |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)       |  |  |  |
| ALCOHOL (UNII: 3K9958V90M)                 |  |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                |  |  |  |
| 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)         |  |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)  |  |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) |  |

| Product Characteristics |       |              |
|-------------------------|-------|--------------|
| Color                   | Score |              |
| Shape                   |       | Size         |
| Flavor                  | ANISE | Imprint Code |
| Contains                |       |              |

| ı | P | Packaging            |  |                         |                       |
|---|---|----------------------|--|-------------------------|-----------------------|
|   | # | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
|   | 1 | NDC:37000-<br>815-12 | 354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |   |                         |                       |  |  |
|-----------------------|---|-------------------------|-----------------------|--|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| OTC Monograph Drug    | M012  | 07/21/2014              |                       |  |  |

| Marketing Information |   |                         |                       |  |  |
|-----------------------|---|-------------------------|-----------------------|--|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| OTC Monograph Drug    | M012  | 07/31/2014              |                       |  |  |
|                       |   |                         |                       |  |  |

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

| Establishment              |         |           |                                    |  |  |  |  |
|----------------------------|---------|-----------|------------------------------------|--|--|--|--|
| Name                       | Address | ID/FEI    | <b>Business Operations</b>         |  |  |  |  |
| Hood Container Corporation |         | 129850751 | pack(37000-045) , label(37000-045) |  |  |  |  |

Revised: 10/2023 The Procter & Gamble Manufacturing Company