

**SEVERE COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci liquid
Family Dollar (FAMILY WELLNESS)**

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.

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine succinate 12.5 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal Decongestant

Uses

- temporarily relieves common cold/flu symptoms:
 - nasal congestion
 - sore throat
 - headache
 - sinus congestion and pressure
 - minor aches and pain
 - runny nose and sneezing
 - cough due to minor throat and bronchial irritation
- temporarily reduces
 - fever
 - cough to help you sleep
 - swelling of nasal passage
- 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 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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

- 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.
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an 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
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not use more than directed (see overdose warning)**
- 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

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or last more than 3 days
- redness or swelling is present
- cough comes back, or occurs with rash or headache that lasts.

These could be a signs of a serious conditions.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- **take only as directed - see Overdose warning**
- do not exceed 4 doses per 24 hours
- measure only with dosing cup provided. Do not use any other dosing device.
- mL = milliliter
- keep dosing cup with product
- adults and children 12 years and over: 30 mL every 4 hours
- children under 12 years of age: do not use
- **When using Day Time or Night Time products, carefully read each label to ensure correct dosing.**

Other information

- **each 30 mL contains;** sodium 64 mg
- store between 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients

anhydrous citric acid, FD&C blue1, FD&C red 40, Flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® NYQUIL® SEVERE COLD & FLU*

NIGHTTIME

Severe Cold & Flu Relief

Acetaminophen 650 mg Pain Reliever/Fever Reducer

Dextromethorphan HBr 20 mg Cough Suppressant

Doxylamine Succinate 12.5 mg Antihistamine

Phenylephrine HCl 10 mg Nasal Decongestant

Relieves

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal/Sinus Congestion & Sinus Pressure
- Sneezing
- Runny Nose
- Cough

Alcohol Free

Max Strength

For Ages 12 Years & Over

BERRY

FL OZ (mL)

*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks® and NyQuil® are registered trademarks of The Procter & Gamble Company.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUPOR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY:

MIDWOOD BRANDS, LLC

10611 MONROE RD,

MATTHEWS, NC 28105

Product Label

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

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 MATTHEWS, NC 28105

PARENTS:
 Learn about teen medicine abuse
www.StopMedicineAbuse.org

NOT 100% SATISFIED?

Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.



Drug Facts (continued)

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← PEEL HERE **Drug Facts (continued under label)**

COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® NYQUIL® SEVERE COLD & FLU®

NDC 55319-416-08

FAMILY
wellness™

NIGHTTIME

Severe Cold & Flu Relief

Acetaminophen 650 mg
 Pain Reliever/Fever Reducer
Dextromethorphan HBr 20 mg
 Cough Suppressant
Doxylamine Succinate 12.5 mg
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 Nasal decongestant

Relieves

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal/Sinus Congestion & Sinus Pressure
- Sneezing • Runny Nose • Cough

BERRY
 Alcohol Free
 Max Strength
 For Ages 12 Years & Over



8 FL OZ (237 mL)

Drug Facts

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Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant

Uses ■ temporarily relieves common cold/flu symptoms
 ■ nasal congestion ■ sore throat ■ headache ■ sinus congestion and pressure ■ minor aches and pains ■ runny nose and sneezing
 ■ cough due to minor throat and bronchial irritation ■ temporarily reduces ■ fever ■ cough to help you sleep ■ 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 4,000 mg of 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.

Drug Facts (continued)

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 ■ a sodium- restricted diet

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Drug Facts (continued)

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- mL = milliliter ■ keep dosing cup with product
- adults and children 12 years and over: 30 mL every 4 hours
- children under 12 years of age: do not use
- when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

Other information

- each 30 mL contains: sodium 64 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments?

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FAMILY WELLNESS Nighttime Severe Cold & Flu Relief

SEVERE COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-416
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1VS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-416-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2015	12/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/31/2015	12/31/2025

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)