

**TOPCARE NITE TIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution**  
**Topco Associates LLC**

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**Topco Associates LLC. Nite Time 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 and pressure
- minor aches and pains
- headache
- fever
- sore throat
- runny nose and sneezing
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose

**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.
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

### **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 such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- 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 (1-800-222-1222). 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 – see Overdose warning
- 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 contains:** sodium 41 mg
- store at 20-25°C (68-77°F)

**Inactive ingredients**

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

**Questions?**

**1-888-423-0139**

# Package/Label Principal Display Panel

TopCare® health

COMPARE TO VICKS® NYQUIL® SEVERE ACTIVE INGREDIENTS

MAXIMUM STRENGTH RELIEF

Nite Time Cold & Flu

SEVERE

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr

ANTIHISTAMINE - DOXYLAMINE SUCCINATE

NASAL DECONGESTANT - PHENYLEPHRINE HCl

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

12 FL OZ (355 mL)

MIXED BERRY FLAVOR

**Drug Facts** (continued)

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 (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

<b>Directions</b> ■ take only as directed – see Overdose warning	■ 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 contains: sodium 41 mg ■ store at 20-25°C (68-77°F)

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

**Questions?** 1-888-423-0139

**PARENTS:** Learn about teen medicine abuse [www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

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GLUTEN FREE • Alcohol Free

**QUALITY GUARANTEED**

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil® Severe.

NDC 36800-763-40



COMPARE TO VICKS® NYQUIL® SEVERE ACTIVE INGREDIENTS\*

**MAXIMUM STRENGTH RELIEF**

# Nite Time Cold & Flu

**SEVERE**

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN  
COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr  
ANTIHISTAMINE - DOXYLAMINE SUCCINATE  
NASAL DECONGESTANT - PHENYLEPHRINE HCl

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



**12 FL OZ (355 mL) MIXED BERRY FLAVOR**

**Drug Facts** **DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

Active ingredients (in each 30 mL)	Purpose
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 ■ sinus congestion and pressure ■ headache ■ fever  
 ■ minor aches and pains ■ sore throat ■ runny nose and sneezing  
 ■ cough due to minor throat and bronchial irritation ■ cough to help you sleep  
 ■ reduces swelling of nasal passages ■ promotes nasal and/or sinus drainage  
 ■ temporarily restores freer breathing through the nose

**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. ■ 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. ■ if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if you have** ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ cough that occurs with too much phlegm (mucus) ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema ■ a sodium-restricted diet

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-763
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	RED (clear, dark)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-763-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/22/2014	08/31/2021

2	NDC:36800-763-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2014
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/09/2014	

**Labeler** - Topco Associates LLC (006935977)

Revised: 10/2024

Topco Associates LLC