

**TOPCARE NITE TIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate liquid**

**Topco Associates LLC**

*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.*

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**Topco Nite Time Cold and Flu Liquid Drug Facts**

**Active ingredient (in each 15 mL tablespoon)**

Acetaminophen 500 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

**Uses**

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

**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
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Sore throat warning: If sore throat is severe, persists for more than two 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 sleepy

**Ask a doctor before use if you have**

- liver disease
- 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 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**

- 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**

- pain 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 recommended – see Liver warning
- use dose cup
- do not exceed 4 doses per 24 hours

adults and children 12 years and over	30 mL (2 TBSP) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

**Other information**

- each TBSP contains: sodium 18 mg
- store at 20°-25°C (68°-77°F)

**Inactive ingredients**

alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

**Questions or comments?**

1-888-423-0139

**Principal Display Panel**

See New Warnings Information

Cold & Flu

Multi-Symptom Relief

Nite Time

Pain Reliever, Fever Reducer - Acetaminophen

Cough Suppressant/Dextromethorphan HBr

Antihistamine/Doxylamine Succinate

Original Flavor

Compare to Vicks® NyQuil® active ingredients

10% Alcohol

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

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



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This TOPCARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

DISTRIBUTED BY TOPCO ASSOCIATES LLC  
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SEE NEW WARNINGS INFORMATION

NDC 36800-908-38

**COLD & FLU**

**MULTI-SYMPTOM RELIEF**

# Nite Time

• Pain Reliever → Acetaminophen  
• Fever Reducer  
• Cough Suppressant / Dextromethorphan HBR  
• Antihistamine / Doxylamine Succinate

Original Flavor



COMPARE TO VICKS® NYQUIL® active ingredients\*

10 FL OZ (296 mL) 10% ALCOHOL

**Drug Facts**

Active ingredients (in each 15 mL tablespoon)	Purpose
Acetaminophen 500 mg	Pain reliever/fever reducer
Dextromethorphan HBR 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

**Uses** temporarily relieves common cold/flu symptoms:

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- minor aches and pains
- sore throat
- fever
- runny nose and sneezing
- headache

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PEEL BACK AT CORNER FOR MORE INFORMATION →

**Drug Facts (continued)**

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**Drug Facts (continued)**

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**Inactive ingredients** alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

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

**Nite Time Cold and Flu Liquid Label**

## TOPCARE NITE TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-908
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 15 mL
DOXYLAMINE SUCCINATE (UNII: Y0R10RE5YD) (DOXYLAMINE SUCCINATE - UNII:Y0R10RE5YD)		6.25 mg

DOXYLAMINE SUCCINATE (UNII: V9B19B5Y1Z) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	0.25 mg in 15 mL
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### Product Characteristics

<b>Color</b>	GREEN (Bright)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-908-30	177 mL in 1 BOTTLE		
2	NDC:36800-908-38	296 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/19/2006	

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

Revised: 5/2009

Topco Associates LLC