

# **TOPCARE NITE TIME COUGH- dextromethorphan hydrobromide, doxylamine succinate solution**

**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 Associates LLC. Nite Time Drug Facts**

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

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

### **Purpose**

Cough suppressant

Antihistamine

### **Uses**

temporarily relieves cold symptoms:

- cough due to minor throat and bronchial irritation
- runny nose and sneezing

### **Warnings**

#### **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.

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

- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

#### **Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers

### **When using this product**

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

### **Stop use and as a doctor if**

cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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 (1-800-222-1222).

### **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 32 mg
- store at 20-25°C (68-77°F)

### **Inactive ingredients**

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, 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

TopCare® health

COMPARE TO VICKS® NYQUIL® COUGH ACTIVE INGREDIENTS

ALL NIGHT COUGH RELIEF

Nite Time Cough

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr

ANTIHISTAMINE - DOXYLAMINE SUCCINATE

- Cough
- Sneezing
- Runny Nose

ALCOHOL 10%

12 FL OZ (355 mL)

CHERRY FLAVOR

**Drug Facts** (continued)

If pregnant or breast-feeding, ask a health professional before use.

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

NDC 36800-668-40



COMPARE TO VICKS® NYQUIL®  
COUGH ACTIVE INGREDIENTS\*

**ALL NIGHT COUGH RELIEF**

## Nite Time Cough

COUGH SUPPRESSANT-  
DEXTROMETHORPHAN HBr  
ANTIHISTAMINE-  
DOXYLAMINE SUCCINATE

- Cough
- Sneezing
- Runny Nose

ALCOHOL 10%

**12 FL OZ (355 mL)**



**CHERRY FLAVOR**

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

**Drug Facts**

Active ingredients (in each 30 mL)	Purpose
Dextromethorphan HBr 30 mg.....	Cough suppressant
Doxylamine succinate 12.5 mg.....	Antihistamine

**Uses** temporarily relieves cold symptoms:

- cough due to minor throat and bronchial irritation
- runny nose and sneezing

**Warnings**

**Do not use**

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

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**Stop use and ask a doctor if** cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition. ▶

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Visit here for more information:  
<http://topbrnds.com/49011>

**GLUTEN FREE** ✓ **QUALITY GUARANTEED**

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

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<b>TOPCARE NITE TIME COUGH</b> dextromethorphan hydrobromide, doxylamine succinate solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-668

Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>	RED (Dark Red)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-668-38	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2004	11/02/2011
2	NDC:36800-668-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2012	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/10/2002	

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

