

**NIGHTTIME COUGH ALL NIGHT COUGH RELIEF- dextromethorphan hydrobromide, doxylamine succinate liquid  
P & L Development, 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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**Drug Facts**

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

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

**Purposes**

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

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

taking sedative or tranquilizers.

**When using this product**

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

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

cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

### **If pregnant 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 (1800-222-1222) right away.

### **Directions**

- keep dosing cup with product
- do not take more than 4 doses in any 24-hour period
- take only as directed
- measure only with dosing cup provided. Do not use any other dosing device.
- mL = milliliter
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years of age: do not use

### **Other information**

- **each 30 mL contains;** sodium 29 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

### **Inactive ingredients**

alcohol, citric acid, FD&C blue 1, FD&C red 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

### **Principal Display Panel**

Compare to active ingredients in Vicks® NyQuil® Cough\*

### **Night Time**

#### **Cough**

all night cough relief

Dextromethorphan HBr

Doxylamine succinate

Relieves:

- cough
- runny nose
- sneezing

for ages 12 and over

nighttime relief

alcohol 10%

FL OZ (mL)

cherry flavor

\*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 BOTTLE OR UNDER CAP IS BROKEN OR MISSING.**

Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

**Product Label**

**Drug Facts** TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

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 Dextromethorphan HBr 30 mg.....Cough suppressant  
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**Purposes**

**Uses** ■ temporarily relieves cold symptoms  
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 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  
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NDC 49580-0345-4  
 Compare to active ingredients in  
**Vicks® NyQuil® Cough\***

**night time cough**  
 all night cough relief

dextromethorphan HBr  
 doxylamine succinate

relieves

- cough
- runny nose
- sneezing

for ages 12 and over  
 nighttime relief  
 alcohol 10%

4 fl oz (118 mL)

cherry flavor

**Drug Facts (continued)**

- cough that occurs with too much phlegm (mucus)
- trouble urinating due to enlarged prostate gland

**Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.**

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Manufactured by:  
**PL Developments**  
 11865 S. Alameda St  
 Lynwood, CA 90262



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

**Drug Facts (continued)**

**When using this product**

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

**Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. 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.**  
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**Drug Facts (continued)**

**Directions** ■ keep dosing cup with product  
 ■ do not take more than 4 doses in any 24-hour period ■ take only as directed  
 ■ measure only with dosing cup provided. Do not use any other dosing device. ■ mL = milliliter  
 ■ adults and children 12 years and over: 30 mL every 6 hours  
 ■ children under 12 years of age: do not use

**Other information**  
 ■ each 30 mL contains: sodium 29 mg  
 ■ store between 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients** alcohol, citric acid, FD&C blue #1, FD&C red #40, flavors, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

**Questions or comments?**  
 Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

**READYIN CASE Nighttime Cough Cherry Flavor**

<b>NIGHTTIME COUGH ALL NIGHT COUGH RELIEF</b>			
dextromethorphan hydrobromide, doxylamine succinate liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49580-0345
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
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: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)		DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
<b>Inactive Ingredients</b>			
Ingredient Name			Strength

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

### Product Characteristics

<b>Color</b>		<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:49580-0345-1	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2014	12/31/2024
2	NDC:49580-0345-6	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2014	12/31/2024
3	NDC:49580-0345-2	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2014	12/31/2024
4	NDC:49580-0345-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2014	12/31/2024

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2014	12/31/2024

**Labeler** - P & L Development, LLC (101896231)