

**NIGHT TIME COUGH- dextromethorphan hydrobromide, doxylamine succinate liquid**

**P & L Development, LLC**

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**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
- a breathing problem or chronic cough that lasts or as occurs with smoking, 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 sedatives or tranquilizers.

**When using this product**

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

- alcohol, sedatives, and tranquilizers may increase drowsiness

**Stop use and ask a doctor if**

- cough lasts more than 7 days, come 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.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions**

- 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°). 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

**Questions or comments?**

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

**Principal Display Panel**

Compare to active ingredients in Vicks'<sup>®</sup> Nyquil<sup>®</sup> Cough\*

**NightTime Cough****all night cough relief**

dextromethorphan HBr

doxylamine succinate

relieves

- cough
- runny nose & sneezing

for ages 12 and over

alcohol 10%

cherry flavor

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 BOTTLE OR UNDER CAP IS BROKEN OR MISSING.**

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

## Product Label

<b>Drug Facts (continued)</b>
<b>Directions</b> ■ do not take more than 4 doses in any 24-hour period ■ measure only with dosing cup provided. Do not use any other dosing device. ■ keep dosing cup with product ■ take only as directed ■ mL = milliliter ■ adults and children 12 years and over: 30 mL every 6 hours ■ children under 12 years of age: do not use
<b>Other information</b> ■ each 30 mL contains: sodium 29 mg ■ store between 20-25°C (68-77°F). Do not refrigerate.
<b>Inactive ingredients</b> 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
<b>Questions or comments?</b> Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

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

**PARENTS:**  
Learn about your medicine here.  
[www.StopTheCommonAbuse.org](http://www.StopTheCommonAbuse.org)

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**PL Developments**  
200 Hicks Street  
Westbury, NY 11590



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

NDC 49580-0499-2

nighttime  
cough  
all night cough relief

dextromethorphan HBr  
cough suppressant  
doxylamine succinate  
antihistamine

relieves:

- cough
- runny nose & sneezing

for ages 12 years & over  
alcohol 10%

12 fl oz (355 mL)



cherry flavor

**READYinCASE NightTime Cough**

<b>Drug Facts</b>	
<b>Active ingredients (in each 30 mL)</b>	<b>Purposes</b>
Dextromethorphan HBr 30 mg.....	Cough suppressant
Doxylamine succinate 12.5 mg.....	Antihistamine
<b>Uses</b> ■ temporarily relieves cold symptoms ■ cough due to minor throat and bronchial irritation ■ runny nose and sneezing	
<b>Warnings</b> <b>Do not use</b> 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. <b>Ask a doctor before use if you have</b> ■ glaucoma ■ 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 ■ trouble urinating due to enlarged prostate gland <b>Ask a doctor or pharmacist before use if you are</b> taking sedatives or tranquilizers.	
<b>When using this product</b> ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery	
<b>Stop use and ask a doctor if</b> 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. <b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	

## NIGHT TIME COUGH

dextromethorphan hydrobromide, doxylamine succinate liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49580-0499
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<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: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	

## 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:49580-0499-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2017	12/31/2025
2	NDC:49580-0499-2	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2017	12/31/2025

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	12/31/2017	12/31/2025

