

**NIGHTTIME COUGH RELIEF CHERRY- dextromethorphan hbr, doxylamine succinate liquid**  
**Pharmacy Value Alliance, 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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**Nighttime Cough Relief**

***Drug Facts***

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

Dextromethorphan HBr 30 mg

Doxylamine Succinate 12.5 mg

***Purpose***

Dextromethorphan HBr Cough suppressant

Doxylamine Succinate Antihistamine

***Uses*** temporarily relieves cold symptoms:

- runny nose and sneezing
- cough

***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.

- to make a child sleepy

***Ask a doctor before use if you have*** • a sodium restricted diet

- 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.

***Ask a doctor or pharmacist before use***

- if you are taking sedatives or tranquilizers

***When using this product***

**• do not use more than directed**

- 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, comes back, or occurs with fever, 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**

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***Directions*** • Use dose cup or tablespoon (TBSP)

- do not exceed 4 doses per 24 hours
- When using Day Time and Night Time products, carefully read each label to ensure correct dosing.

adults & 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

***Other information***

- **each 30 mL dose cup contains:** sodium 45 mg
- store at room temperature

***Inactive ingredients*** citric acid, FD&C Blue No. 1, FD&C Red No. 40, .flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

**Questions?** Call weekdays from 9:30 am to 4:30 pm  
EST. **1-877-798-5944.**

**Principal Display Panel**

**Premier Value®**

COMPARE TO THE ACTIVE  
INGREDIENTS IN  
VICKS® NYQUIL®\* COUGH\*

**COUGH**

**Nighttime Cough Relief**

Dextromethorphan HBr..... Cough Suppressant  
Doxylamine Succinate .....Antihistamine

- Cough
- Sneezing
- Runny Nose

**Cherry Flavor**

**8 FL OZ (237 mL)**

**INDEPENDENTLY TESTED**

**PV**

**SATISFACTION GUARANTEED**

**DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN**

**Failure to follow these warnings could result in serious consequences**

**Questions?** Call weekdays **1-877-798-5944.**

\*This product is not manufactured or distributed by  
Proctor & Gamble owner of the registered  
trademark Vicks® NyQuil® Cough

DISTRIBUTED BY:  
PHARMACY VALUE ALLIANCE, LLC  
407 EAST LANCASTER AVENUE,  
WAYNEPA 19087

INDEPENDENTLY TESTED  
 PV  
 SATISFACTION GUARANTEED

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

LR-039  
 REV 01

Product Label - Nighttime Cough Relief - 8 OZ Package

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COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® NYQUIL® COUGH\*

# COUGH

## Nighttime Cough Relief

Dextromethorphan HBr..... Cough Suppressant  
 Doxylamine Succinate.....Antihistamine

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- Sneezing
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Cherry Flavor  
 8 FL OZ (237 mL)




**Drug Facts (continued)**

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LR-039  
 REV 01



8 40986 03479 4

→ DRUG FACTS CONTINUED ON BACK →

Peel Here


**Drug Facts (continued)**

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# NIGHTTIME COUGH RELIEF CHERRY

dextromethorphan hbr, doxylamine succinate liquid

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-238
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-238-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2018	

**Labeler** - Pharmacy Value Alliance, LLC (101668460)

**Registrant** - Aptapharma Inc. (790523323)

**Establishment**

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(68016-238)

Revised: 10/2018

Pharmacy Value Alliance, LLC