

NIGHTTIME COUGH RELIEF CHERRY- dextromethorphan hbr, doxylamine succinate liquid

Pharmacy Value Alliance, LLC

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

*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

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN
 Failure to follow these warnings could result in serious consequences

Drug Facts	
Active ingredients (in each 30 mL dose cup)	Purpose
Dextromethorphan HBr 30 mg.....Cough suppressant	
Doxylamine Succinate 12.5 mg.....Antihistamine	
Uses temporarily relieves cold symptoms:	
<ul style="list-style-type: none"> • runny nose and sneezing • cough 	
Warnings	
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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.	
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When using this product	
<ul style="list-style-type: none"> • 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 	



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)




Drug Facts (continued)

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.**

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



8 40986 03479 4

LR-039
REV 01

→ DRUG FACTS CONTINUED ON BACK →

Peel Here

Drug Facts (continued)

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.

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Premier Value® Nighttime Cough Relief Cherry Flavor

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN
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Drug Facts

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Dextromethorphan HBr 30 mg.....	Cough suppressant
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Ask a doctor before use if you have • a sodium restricted diet
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Ask a doctor or pharmacist before use
 • if you are taking sedatives or tranquilizers

When using this product
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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)




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: V9B19B5Y12) (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 Drug	M012	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)