NIGHTTIME COUGH- dextromethorphan hbr, doxylamine succinate liquid
AptaPharma Inc.

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.

Nighttime Cough

Drug Facts

Active ingredients (in each 30 mL)
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 an 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 amotor vehicle or operating machinery • alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if • redness or swelling is present • cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of aserious condition.

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

Keep out of reach of children

Keep out of reach of children.

Directions
• use dose cup
• do not exceed 4 doses per 24 hours
• When using Day Time and Night Time products, carefully read each label to ensure correct dosing.
- mL= milliliter

Age	Dose
Adults & children 12 years and over	30 mL every 6 hours
Children 4 to under 12 years	Ask a doctor
Children under 4 years of age	Do not use

Other information
• **each 30 mL contains:** sodium 10 mg
• store at room temperature
• dosing cup provided

Inactive ingredients
Anhydrous citric acid, flavor, purified water, sodium benzoate, sucrose

Ouestions? Call weekdays from 9:30 AM to 4:30 PM EST at **1-877-798-5944**

Principal Display Panel

CVS
HealthTM

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

Nighttime
Cough

Free of alcohol, dyes &
artificial sweeteners

DEXTROMETHORPHAN HBr
Cough suppressant

DOXYLAMINE SUCCINATE
Antihistamine

Relieves:
• Cough
• Sneezing
• Runny nose

Cherry Flavor

ForAges
12 & Over

8 FL OZ (237 mL)

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

*This product is not manufactured or distributed by Proctor & Gamble, owner of the registered trademarks Vicks® and NyQuil®.

Lot:
Exp:

LR-106 #442933

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895

CVS.com® 1-800-SHOP CVS
V-34874

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Moneu Back Guarantee

Nighttime Cough Relief by CVS Pharmacy, Inc.

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NIGHTTIME COUGH

dextromethorphan hbr, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76281-308
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)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76281-308-26	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2018	

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-308)

Revised: 10/2018 AptaPharma Inc.