

NIGHTTIME COUGH- dextromethorphan hydrobromide, doxylamine succinate liquid
Walgreen Company

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.

Walgreen Co. Nighttime Cough Drug Facts

Active ingredient (in each 15 mL tablespoon)

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose

Cough suppressant

Antihistamine

Uses

temporarily relieves cold symptoms:

- cough
- 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.
- to make a child sleepy

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- do not use more than directed

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- 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 for 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.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take only as recommended
- use dose cup
- do not exceed 4 doses per 24 hours

adults and 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

- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information

- each TBSP contains: sodium 15 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to NyQuil® Cough active ingredients

See Labeling Changes

NightTime Cough
 All Night Cough Relief
 Cough Suppressant, Antihistamine
 Dextromethorphan HBr – Cough
 Doxylamine Succinate – Sneezing, Runny Nose
 Cherry Flavor
 10% Alcohol

Compare to NyQuil® Cough active ingredients*

Walgreens NDC 0363-0668-38

SEE LABELING CHANGES

NIGHTTIME COUGH
ALL NIGHT COUGH RELIEF
 Cough Suppressant, Antihistamine
CHERRY FLAVOR

10 FL OZ (296mL) **10% ALCOHOL**

Drug Facts (continued)
 Stop use and ask a doctor if cough lasts for 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions ■ take only as recommended ■ use dose cup
 ■ do not exceed 4 doses per 24 hours

adults and 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

■ when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information ■ each TBSP contains: sodium 15 mg ■ store at 20°-25°C (68°-77°F)

Inactive Ingredients alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments? 1-800-719-9260

*This product is not manufactured or distributed by Procter & Gamble, distributor of NyQuil® Cough.
 Distributed by: Walgreen Co. 200 Wilmet Rd., Deerfield, IL 60015-4616
 100% Satisfaction Guarantee www.walgreens.com

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Drug Facts
Active ingredients (in each 15 mL tablespoon) **Purpose**
 Dextromethorphan HBr 15 mg.....Cough suppressant
 Doxylamine succinate 6.25 mg.....Antihistamine

Uses temporarily relieves cold symptoms: ■ cough
 ■ 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. ■ to make a child sleepy

Ask a doctor before use if you have ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ cough that occurs with too much phlegm (mucus) ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough as occurs with smoking, asthma or emphysema

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

When using this product ■ do not use more than directed
 ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives and tranquilizers may increase drowsiness

Nighttime Cough Label

NIGHTTIME COUGH

dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0668
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 15 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color	RED (Dark Red)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0668-30	177 mL in 1 BOTTLE		
2	NDC:0363-0668-38	296 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/16/2002	

Labeler - Walgreen Company (008965063)