

**LEADER NIGHTTIME COUGH- dextromethorphan hbr, doxylamine succinate solution**  
**Cardinal Health 110, LLC. dba Leader**

*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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**Cardinal Health Nighttime Cough 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
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, 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**

- excitability may occur, especially in children
- may cause marked drowsiness
- 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 persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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 (1-800-222-1222).

**Directions**

- take only as directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

**Other information**

- **each 30 mL contains:** sodium 32 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**

LEADER™

Nighttime Cough

Dextromethorphan HBr, 30 mg

Doxylamine Succinate, 12.5 mg

Cough Suppressant

Antihistamine

Cherry Flavor

Relief of:

Cough

Sneezing

Runny Nose

COMPARE TO VICKS® NYQUIL® COUGH

active ingredients

ALCOHOL 10%

100% Money Back Guarantee

12 FL OZ (355 mL)

**LEADER NIGHTTIME COUGH**

dextromethorphan hbr, doxylamine succinate solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0193	
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	
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 GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0K00R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM CITRATE, UNSPECIFIED FORM (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:70000-0193-1	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/29/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	11/29/2016		

**Labeler** - Cardinal Health 110, LLC. dba Leader (063997360)

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Leader