# NIGHTTIME COUGH RELIEF- dextromethorphan hbr, doxylamine succinate solution Rite Aid Corporation

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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## **Rite Aid Corporation Nighttime Cough Relief 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

antihistamine

#### **Principal Display Panel**

Compare to the active ingredients of Vicks® NyQuil® Cough nighttime cough relief dextromethorphan HBr doxylamine succinate cough suppressant

cherry flavor all night cough relief multi-symptom relief 10% ALCOHOL 8 FL OZ (237 mL)



#### Drug Facts (continued)

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0668
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
WATER (UNII: 059QF0KO0R)		

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

Packaging					
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1	NDC:11822-0668-1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
ı	2	NDC:11822-0668-2	355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/07/2002	

## Labeler - Rite Aid Corporation (014578892)

Revised: 4/2016 Rite Aid Corporation