CAREONE NIGHTTIME COUGH- dextromethorphan hbr, doxylamine succinate solution
American Sales 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.

American Sales Company 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

Compare to the active ingredients in Vicks® NyQuil® Cough

NIGHTTIME COUGH

Cough Suppressant-Dextromethorphan HBr

Antihistamine-Doxylamine Succinate

10% ALCOHOL

Relieves:

Cough

Sneezing

Runny Nose

Gluten Free

OUR PHARMACISTS RECOMMEND

Cherry Flavor

12 FL OZ (355mL)

CAREONE NIGHTTIME COUGH

dextromethorphan hbr, doxylamine succinate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-995
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 (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:41520-995-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2013	05/16/2016
2	NDC:41520-995-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/18/2004	

Labeler - American Sales Company (809183973)

Revised: 12/2019 American Sales Company