

CAREONE TUSSIN- dextromethorphan hydrobromide 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 Tussin Drug Facts

Active ingredient (in each 10 mL)

Dextromethorphan HBr, USP 30 mg

Purpose

Cough suppressant

Use

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

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

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Stop use and ask a doctor if

cough lasts for more than 7 days, comes back, 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

- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product

- mL = milliliter
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	10 mL every 6 to 8 hours
children under 12 years	do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, menthol, purified water, saccharin sodium, sodium benzoate

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Robitussin® Long-Acting Cough

TUSSIN LONG ACTING COUGH

Cough Suppressant – Dextromethorphan HBr

Relieves Cough For Up to 8hrs

Adult

For Ages 12 & Over

Non-Drowsy

1.4% ALCOHOL

Gluten Free

OUR PHARMACISTS RECOMMEND

Original Flavor

4 FL OZ (118mL)



CAREONE TUSSIN

dextromethorphan hydrobromide solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-903
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 10 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MENTHOL (UNII: L7T10EP3A)	

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-903-26	1 in 1 CARTON	02/08/2018	
1		118 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	02/08/2018	

Labeler - American Sales Company (809183973)

Revised: 2/2018

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