CAREONE TUSSIN DM- dextromethorphan hbr, guaifenesin 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 DM Drug Facts

Active ingredients (in each 20 mL)

Dextromethorphan HBr, USP 20 mg

Guaifenesin, USP 400 mg

Purposes

Cough suppressant

Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

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, chronic bronchitis, 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 6 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	20 mL every 4 hours
children under 12 years	do not use

Other information

- **each 20 mL contains:** sodium 13 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

acetic acid, anhydrous citric acid, carboxymethylcellulose sodium, FD&C blue no. 1, FD&C red no. 40, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredients in Robitussin® Maximum Strength Cough + Chest Congestion DM

TUSSIN DM

COUGH + CHEST CONGESTION

Cough Suppressant-Dextromethorphan HBr

Expectorant-Guaifenesin

Maximum Strength

Relieves:

Cough

Mucus

Adult

For Ages 12 & Over

Non-Drowsy

Alcohol Free

Gluten Free

Same Effective Cough Relief*

*Compared to our previous (10 mL) formula

See New Dosing

OUR PHARMACISTS RECOMMEND

Raspberry & Menthol Flavor

4 FL OZ (118mL)

CAREONE TUSSIN DM

dextromethorphan hbr, guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-931
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	RED	**Score**	
Shape		**Size**	
Flavor	FRUIT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:41520-931-26	1 in 1 CARTON	09/20/2018	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41520-931-34	1 in 1 CARTON	09/20/2018	
2		237 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	09/20/2018	

Labeler - American Sales Company (809183973)

Revised: 12/2019 American Sales Company