TUSSIN DM- dextromethorphan hydrobromide, guaifenes in capsule, liquid filled FOODHOLD U.S.A., LLC

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.

TUSSIN DM

Drug Facts

Active ingredients (in each softgel)

Dextromethorphan HBr, USP 10 mg Guaifenesin, USP 200 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. These could be signs 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.

Directions

- do not take more than 12 softgels in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

adults and children 12 years and over	2 softgels every 4 hours
children under 12 years	do not use

Other information

- store at room temperature 15-30°C (59-86°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

FD&C Red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special and white edible ink

Questions or comments?

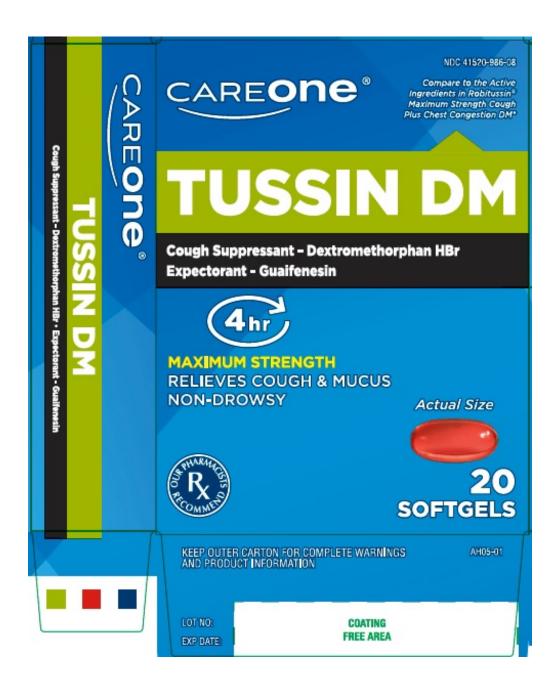
Call: 1-855-215-8180

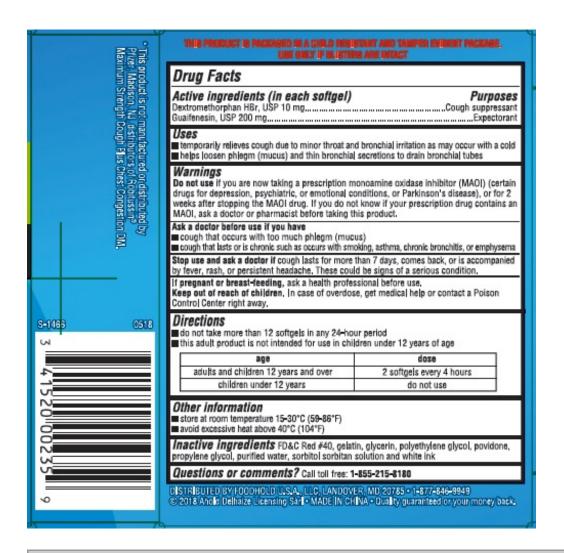
PRINCIPAL DISPLAY PANEL - Carton Label

CAREONE TUSSIN DM 20ct

NDC 41520-986-08

 $^{^*}$ Compare to the active ingredients in Robitussin $^{\circledR}$ Maximum Strength Cough Plus Chest Congestion DM





TUSSIN DM

dextromethorphan hydrobromide, guaifenesin capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-986
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE (UNII: FZ989 GH94E)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	red (clear)	Score	no score
Shape	capsule (oblong)	Size	20 mm
Flavor		Imprint Code	PC37
Contains			

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:41520-986- 08	2 in 1 CARTON	10/02/2016		
l	1	10 in 1 BLISTER PACK; 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	10/02/2016	

Labeler - FOODHOLD U.S.A., LLC (809183973)

Establishment			
Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(41520-986), analysis(41520-986)

Revised: 11/2019 FOODHOLD U.S.A., LLC