

**TUSSIN DM COUGH AND CHEST CONGESTION- dextromethorphan hydrobromide,  
guaifenesin capsule, liquid filled  
PuraCap Pharmaceutical 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.*

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**Tussin DM Cough & Chest Congestion**

**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
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age	dose
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 toll free: 1-855-215-8180

### PRINCIPAL DISPLAY PANEL

Tussin DM Cough & Chest Congestion

NDC 51013-178-08

\*Compare to the active ingredients in Robitussin® Maximum Strength Cough Plus Chest Congestion DM



# TUSSIN DM COUGH AND CHEST CONGESTION

dextromethorphan hydrobromide, guaifenesin capsule, liquid filled

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-178
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (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)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-178-08	2 in 1 CARTON	07/27/2016	
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	07/27/2016	

**Labeler** - PuraCap Pharmaceutical LLC (962106329)

## Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-178) , analysis(51013-178)

Revised: 1/2020

PuraCap Pharmaceutical LLC