

**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.

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
-

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 51013-166-08

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

The image shows a detailed layout of the Tussin DM packaging, including the front panel, side panel, and back panel. The front panel features the Drug Mart logo, the product name "Tussin DM", and the description "Non-Drowsy Adult Cough & Chest Congestion". It also lists the active ingredients: DEXTROMETHORPHAN HBr Cough Suppressant and GUAFENESIN Expectorant. The packaging is labeled as "Maximum Strength" and "Non-Drowsy". A red softgel is shown with the text "Actual Size". The front panel also includes a list of benefits: "Relieves Cough for up to 8 hours", "Relieves Mucus", "Non-Drowsy", and "Non-Narcotic Formula". The quantity is listed as "20 Softgels**" and "Liquid Filled Capsules".

The side panel features the Drug Mart logo and the product name "Tussin DM". It also lists the active ingredients: DEXTROMETHORPHAN HBr Cough Suppressant and GUAFENESIN Expectorant. The side panel also includes a list of benefits: "Relieves Cough for up to 8 hours", "Relieves Mucus", "Non-Drowsy", and "Non-Narcotic Formula". The quantity is listed as "20 Softgels**" and "Liquid Filled Capsules".

The back panel features the Drug Mart logo and the product name "Tussin DM". It also lists the active ingredients: DEXTROMETHORPHAN HBr Cough Suppressant and GUAFENESIN Expectorant. The back panel also includes a list of benefits: "Relieves Cough for up to 8 hours", "Relieves Mucus", "Non-Drowsy", and "Non-Narcotic Formula". The quantity is listed as "20 Softgels**" and "Liquid Filled Capsules".

The back panel also includes a "Drug Facts" section with the following information:

Drug Facts

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Purposes Cough suppressant; Expectorant

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

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*This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of Robitussin® Maximum Strength Cough Plus Chest Congestion DM.

The back panel also includes a "PLEASE RECYCLE" logo and a "COATING FREE AREA" label.

TUSSIN DM COUGH AND CHEST CONGESTION

dextromethorphan hydrobromide, guaifenesin capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-166
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:51013-166-08	2 in 1 CARTON	07/20/2016	
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	07/20/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-166) , analysis(510 13-166)

Revised: 1/2020

PuraCap Pharmaceutical LLC