

COUGH AND CONGESTION DM - dextromethorphan and guaifenesin capsule, liquid filled

Agile Pharmachem

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.

Chest and Cough Congestion

Active Ingredient

(in each liquid filled capsule)

Dextromethorphan Hydrobromide, USP 10mg

Guaifenesin, USP 200mg

Purpose

Cough Suppressant

Expectorant

Uses

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

Directions

- Do not take more than 12 capsules in any 24 hour period
- This adult product is not intend for use in children under 12 years of age

Age	dose
Adults and children 12 years and over	2 capsules every 4 hours
Children under 12 years	Do not use

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 occur with smoking, asthma, chronic bronchitis, or emphysema
- Stop use and ask a doctor if** cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. This 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.

Other Information

- store at 20-25 °C(68-77 °F)
- avoid excessive heat above 40 °C (104°F)

Inactive Ingredients

FD&C Red No 40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, providone (PVP K-30), purified water, special sorbitol, titanium dioxide

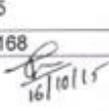
Questions or Comments

Toll free 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Guaifenesin 200 mg & Dextromethorphan Hydrobromide 10 mg soft gelatin Capsules			
Each soft gelatin capsule contains: Guaifenesin USP 200 mg & Dextromethorphan HBr USP 10 mg. Excipients QS			
BATCH NO.	M15ED017 ✓	QUANTITY	25X300 softgels
MFG.DATE	10/2015 ✓	SHIPPER NO.	_____ out of _____
EXP.DATE	09/2017 ✓	GROSS WT.	
		NET WT.	
WARNING: KEEP OUT OF THE REACH OF CHILDREN		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C)	
CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: MEDGEL PRIVATE LIMITED 19-20, SEZ, PHARMA ZONE, PHASE-II, PITHAMPUR, DISTT. DHAR-454775		DISTRIBUTED BY: AGILE PHARMACHEM 116D, SHIROMANI COMPLEX SATELLITE, AHMEDABAD-380015	
MFG. LIC. NO.	MP/DRUGS/25/4/2011	MFG. LIC. NO.	GJ-AD2-98783
LABELLER CODE	51344	NDC No.	58805 -007-75 ✓
SHIPPED TO: VELOCITY PHARMA LLC 228/B, SHERWOOD AVE, FARMINGDALE, NY-11735			
LABELLER CODE	76168		

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Cough and Congestion DM,
NDC:58805-007-75 25*300 Softgel Liquid filled

COUGH AND CONGESTION DM

dextromethorphan and guaifenesin capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58805-007
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
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
POVIDONE (UNII: FZ989GH94E)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED (Light)	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	601
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58805-007-75	7500 in 1 CAPSULE		
1		1 in 1 CARTON; 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	11/08/2015	

