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

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.

Dextromethorphan HBr (Cough Supressant)

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

Cough&Congestion DM

Relieves:
• Mucus
• Cough

non-drousy formula

MAXIMUM STRENTH DM

Chest & Cough Congestion

NDC 76168-060-37

Cough&Congestion DM

Chest & Cough Congestion

Dextromethorphan HBr (Cough Suppressant)
Guaifenesin (Expectorant)

Relieves:
• Mucus
• Cough

non-drousy formula

For ADULTS 12 and OVER

16 Soft Gels

Distributed by: Unimedix Pharma LLC

Cough&Congestion DM

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MAXIMUM STRENTH DM

Chest & Cough Congestion

Drug Facts

Active Ingredients (in each liquid filled capsule) — **Purposes**

Dextromethorphan Hydrobromide, USP 10 mg ..... Cough suppressant
Guaifenesin, USP 200 mg ..... Expectorant

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3120

Cough and Congestion DM,

NDC:76168-060-37 16 Softgel Liquid filled

COUGH AND CONGESTION DM

dextromethorphan and guaifenesin capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-060
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:76168-060-37	16 in 1 BOTTLE	11/08/2015	
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	

Labeler - Velocity Pharma (962198409)

Registrant - Velocity Pharma (962198409)

Revised: 9/2016 Velocity Pharma