COUGH AND CONGESTION DM- dextromethorphan and guaifenes in 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)

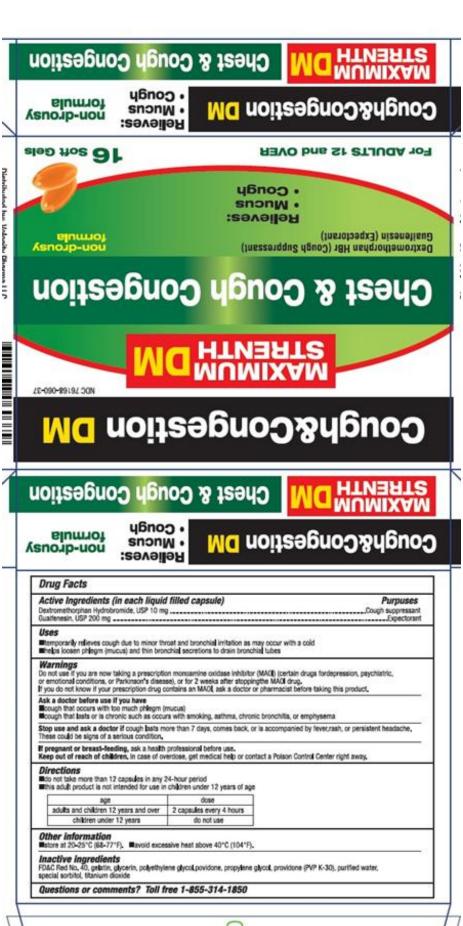
Inactive Ingredients

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



N

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: 9 D2RTI9 KYH) (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)		
PO VIDO NE (UNII: FZ989 GH9 4E)		
PO VIDO NE K30 (UNII: U725QWY32X)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	RED (Light)	Score	no score
Shape	OVAL	Size	20 mm
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				
ı	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