

**GADAVYT COUGH DM- dextromethorphan hydrobromide, guaifenesin liquid**  
**Gadal Laboratories Inc**

*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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**Drug Facts**

<b>Active Ingredient (in each 5 mL tsp.)</b>	<b>Purpose</b>
Dextromethorphan HBr	Cough Suppressant
Guaifenesin 100mg	Expectorant

**USES**

- temporarily quiets cough associated with the common cold or inhaled irritants
- Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

**Warnings**

Ask a doctor before use if

- you have cough that lasts or a chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema.
- cough occurs with too much phlegm (mucus)

**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 you are taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product.

**Stop use and ask a doctor if**

- cough lasts for more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

**Keep out of the reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**If pregnant or breast-feeding,** ask a health professional before use.

**Directions**

do not take more than 6 doses in any 24 hour period

adults and children 12 years and over	2 TSP every 4 hours or as directed by doctor
children under 12 years	do not use

**Other information**

store at room temperature 15 - 30 degrees C (59 - 86 degrees F)

**TAMPER-EVIDENT:** Do not use if seal under cap is torn, broken or missing.

**Inactive Ingredients**

Citric acid, methylparaben, propylparaben, glycerin, sucralose, sodium citrate, FD and C Red No. 40, menthol, natrosol, cherry flavor, purified water

GADAL Laboratories, Inc.

Miami, Fl 33186

www.gadallaboratories.com

NDC 53113-557-04

**Drug Facts**

**Active ingredient (in each 5ml tsp.)**  
Dextromethorphan HBr USP 10 mg.....Cough suppressant  
Guaifenesin USP 100mg.....Expectorant

**Purpose**  
Guaifenesin USP 100mg.....Expectorant

**Uses** • temporarily quiets cough associated with the common cold or inhaled irritants • helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

**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 you are taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product.  
**Ask a doctor before use if** • you have a cough that lasts or a chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema • cough occurs with too much phlegm (mucus)  
**Stop use and ask a doctor if** • cough lasts for more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.  
**if pregnant or breast-feeding**, ask a health professional before use. **Keep out of the reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Gadavyt**  
**Cough Formula**  
**Guaifenesin DM**

**Sugar Free Alcohol Free**

**Adult**

• Expectorant  
• Cough Suppressant

Cherry Flavor  
4 FL OZ (118 ml)

**Directions**  
do not take more than 6 doses in any 24 hour period  
adults and children 12 years and over 2 TSP every 4 hours or as directed by doctor  
Children under 12 years do not use

**Other information**  
• store at room temperature • 15°-30°C (59°-86°F)  
**TAMPER-EVIDENT:** Do not use if seal under cap is torn, broken or missing.

**Inactive ingredients**  
Citric acid, methylparaben, propylparaben, glycerin, sucralose, sodium citrate, FD&C Red#40, menthol, natrosol, cherry flavor, purified water.



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**MANUFACTURED BY:** SSS GROUP, LLC.  
Miami, FL 33186  
www.gadallaboratories.com

**Lot No.:**  
**Exp. Date:**

## GADAVYT COUGH DM

dextromethorphan hydrobromide, guaifenesin liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53113-557
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HYDROXYETHYL CELLULOSE (2000 MPAS AT 1%)</b> (UNII: S38J6RZN16)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (Cherry Flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-557-04	118 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/01/2012	

**Labeler** - Gadal Laboratories Inc (841305639)

Revised: 12/2012

Gadal Laboratories Inc