

**MUCUS RELIEF COUGH AND CONGESTION DM- guaifenesin and dextromethorphan  
hbr tablet**

**Richmond Pharmaceuticals, 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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**Guaifenesin 400 mg - DextromethorphanCaplets 20 mg Caplets**

***Active ingredients (in each caplet)***

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

***Purpose***

Cough suppressant

Expectorant

***Uses***

- temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
- 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 your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- cough accompanied by too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**When using this product**

do not use more than directed.

**Stop use and ask a doctor if**

cough lasts more than 7 days, comes back, or occurs with 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***

- take with a full glass of water
- **adults and children 12 years of age and over:** 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
- **children under 12 years:** do not use

***Other information***

- store at 15°-30°C (59°-86°F)

***Inactive ingredients***

Colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, stearic acid

***Questions or comments?***

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

***Principal Display Panel***

Mucus Relief Cough and Congestion DM

NDC- 54738-985-30.....30 caplets

NDC 54738-985-30

**GUAIFENESIN**  
**400 mg**  
**&**  
**DEXTROMETHORPHAN HBr**  
**20 mg**  
 Expectorant &  
 Cough Suppressant  
**30 CAPLETS**

Richmond Pharmaceuticals, Inc.

**Drug Facts (continued)**

■ cough accompanied by too much phlegm (mucus)

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious illness.

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 6 doses in any 24-hour period

■ this product is not intended for use in children under 12 years of age

■ adults & children 12 years and over: 1 caplet every 4 hours

■ children under 12 years: do not use

**Other information**

■ store at 15°-30°C (59°-86° F)

**Inactive ingredients** colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, stearic acid

**Questions or comments?**

call 800-270-4498, 8:30 am – 4:30 pm ET, Monday – Friday

TOP LAYER

**Drug Facts**

**Active ingredients (in each caplet)**

Dextromethorphan HBr 20 mg ... Cough Suppressant  
 Guaifenesin 400 mg ..... Expectorant

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and 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 your prescription drug contains an MAOI, ask a doctor or pharmacist before using this product.

**Ask a doctor before use if you have**

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Drug Facts (continued on back of label)

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Distributed By: Richmond Pharmaceuticals, Inc.  
Richmond, VA 23233 USA

LR0116



SEE HERE FOR MORE DRUG FACTS

NO UV AREA

NDC- 54738-985-60....60 caplets

NDC 54738-985-60

**GUAIFENESIN  
400 mg  
&  
DEXTROMETHORPHAN HBr  
20 mg**

Expectorant &  
Cough Suppressant

**60 CAPLETS**

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Richmond Pharmaceuticals, Inc.

<b>Drug Facts</b>	<b>Purposes</b>	<b>Uses</b>	<b>Warnings</b>
<b>Active ingredients (in each caplet)</b> Dextromethorphan HBr 20 mg ... Cough Suppressant Guaifenesin 400 mg ..... Expectorant	temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold	helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive	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 using this product.
			Ask a doctor before use if you have <ul style="list-style-type: none"> <li>■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema</li> </ul>

Drug Facts (continued on back of label)

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

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PEEL HERE FOR MORE DRUG FACTS

**NO UV AREA**

LR0116

TOP LAYER

<b>Drug Facts (continued)</b>	<b>Directions</b>	<b>Other information</b>	<b>Inactive ingredients</b>
<ul style="list-style-type: none"> <li>■ cough accompanied by too much phlegm (mucus)</li> </ul> <p>Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious illness.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	<ul style="list-style-type: none"> <li>■ do not take more than 6 doses in any 24-hour period</li> <li>■ this product is not intended for use in children under 12 years of age</li> <li>■ adults &amp; children 12 years and over: 1 caplet every 4 hours</li> <li>■ children under 12 years: do not use</li> </ul>	<ul style="list-style-type: none"> <li>■ store at 15°-30°C (59°-86°F)</li> </ul>	colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, stearic acid
			<b>Questions or comments?</b> call 804-270-4488, 8:30 am - 4:30 pm ET, Monday - Friday

<b>MUCUS RELIEF COUGH AND CONGESTION DM</b>			
guaifenesin and dextromethorphan hbr tablet			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54738-985
Route of Administration	ORAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	

<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTO DEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	AP;150
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-985-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2016	
2	NDC:54738-985-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2016	

**Labeler** - Richmond Pharmaceuticals, Inc (043569607)

**Registrant** - Advance Pharmaceutical Inc. (078301063)

### Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-985)