

# **QUALITY CHOICE MUCUS RELIEF DM DM- dextromethorphan hydrobromide / guaifenesin tablet**

## **Chain Drug Marketing Association**

*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**

### **Active ingredient** - (per tablet)

Dextromethorphan Hydrobromide 20mg

Guaifenesin 400mg

### **Purpose**

Cough Suppressant

Expectorant

## **Uses**

- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold
- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- Helps make coughs more productive.

## **Warnings**

**Do not use** ■ if you are now taking a prescription monoamine oxidase (inhiMor~MAIO) (Certain drugs for depression, psychiatric or emotional conditioners or Parkinson's disease) or for 2 weeks after stopping MAIO drug, If you do not know if your prescription drug contains an MAIO, ask your doctor or pharmacist before using this product.

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

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

### **Stop use and ask doctor if**

- symptoms are accompanied by fever, rash or persistent headache
- cough persists for more than 1 week or tends to recur.

**A persistent cough may be a sign 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 Center immediately.

**Directions**

■ **Adults and children 12 years of age and over:** take 1 tablet every 4 hours as needed.

■ **Children 6 to 10 under 12 years of age:** take 1/2 tablet every 4 hours as needed.

■ **Children under 6 years of age:** consult a doctor.

**Do not exceed 6 doses in a 24 hour period or as directed by a doctor**

**Other Information**

Store at 15°-30°C (59°-86°F)

**Inactive Ingredients** magnesium stearate, microcrystalline cellulose. May also contain (colloidal) silicon dioxide, (co) povidone, dicalcium phosphate, maltodextrin, sodium starch glycolate, stearic acid.



## QUALITY CHOICE MUCUS RELIEF DM DM

dextromethorphan hydrobromide / guaifenesin tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-753
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)		Guaifenesin	400 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)				
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)				
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)				
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)				
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)				
<b>Product Characteristics</b>				
<b>Color</b>	white	<b>Score</b>	2 pieces	
<b>Shape</b>	OVAL	<b>Size</b>	17mm	
<b>Flavor</b>		<b>Imprint Code</b>	PH073	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63868-753-50	1 in 1 CARTON	08/01/2012	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341		08/01/2012	

**Labeler** - Chain Drug Marketing Association (011920774)

**Registrant** - Reese Pharmaceutical Co (004172052)

## Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(63868-753)