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.

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 emphysma
■ 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.

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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
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	400 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	PH073
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-753-50	1 in 1 CARTON	08/01/2012	
1		50 in 1 BOTTLE; 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	08/01/2012	

Labeler - Chain Drug Marketing Association (011920774)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(63868-753) , repack(63868-753)

Establishment

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