

PREMIER VALUE CHEST CONGESTION AND COUGH RELEIF DM- dextromethorphan hydrobromide / guaifenesin tablet
Reese Pharmaceutical Co

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) - Purpose

Dextromethorphan Hydrobromide 20mg Cough Suppressant

Guaifenesin 400mg Expectorant

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 (mucous)

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

Do not use if you are now taking a prescription monoamine oxidase (inhibitor-MAO)

Certain drugs for depression, psychiatric or emotional conditions or Parkinson's disease
or for 2 weeks after stopping MAO drug, If you do not know if your prescription drug contains
an MAO, ask your doctor or pharmacist before using this product.

Keep out of reach of children, In case of overdose, get medical help or contact a Poison Center
immediately

If pregnant or breastfeeding, ask a health professional before use.

magnesium stearate, microcrystalline cellulose,

May also contain (colloidal) silicon dioxide, (co) povidone, dicalcium
phosphate, maltodextrin, sodium starch glycolate, stearic acid

Directions

• Adults and children 12 years of age and over:

take 1 tablet every 4 hours as needed

• Children 6 to 11 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) Rev 10/U9 RCCF

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

Purpose

Cough Suppressant

Expectorant

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.

Caution: do not use. If imprinted seal under cap is broken or missing

Drug Facts	Purpose Cough suppressant Expectorant
Active ingredients (per caplet) Dextromethorphan HBr 20mg Guaifenesin 400mg	
Uses	Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold. Relaxes phlegm (mucus) and thin bronchial secretions to do the bronchial passages of bothersome mucus. Helps 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 asthma or emphysema, or if you have chronic bronchitis or emphysema. Cough is accompanied by fever, rash or persistent headache. 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 Control Center immediately.
Directions	Adults and children 12 years of age and over: Take 2 caplets every 4 to 6 hours as needed. Children 6 to under 12 years of age: take 1/2 caplet 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, polyethylene glycol, silicon dioxide, croscarmellose sodium, croscarmellose sodium starch glycolate, stearic acid, REV-AGE RECV

For any reason you are not satisfied with the product, please return it to the store where purchased for a full refund.

DISTRIBUTED BY:
CHAM DRUG CONSORTIUM, LLC
2300 N.W. CORPORATE BLVD., STE. 115
BOCA RATON, FL 33431

8 409861 0201 11 7

Premier Value
CHEST CONGESTION AND COUGH RELIEF
COUGH SUPPRESSANT AND COUGH RELIEF
Dextromethorphan HBr 20mg
EXPECTORANT
400mg Guaifenesin

- Immediate Release Caplets
- Loosens & Relieves Chest Congestion
- Makes Coughs More Productive
- Controls Cough
- Dye-free

50 Caplets
Provides up to 2400mg Guaifenesin and 120mg Dextromethorphan daily

Premier Value
CHEST CONGESTION AND COUGH RELIEF
COUGH SUPPRESSANT AND COUGH RELIEF
Dextromethorphan HBr 20mg
EXPECTORANT
400mg Guaifenesin

- Immediate Release Caplets
- Loosens & Relieves Chest Congestion
- Makes Coughs More Productive
- Controls Cough
- Dye-free

50 Caplets
Provides up to 2400mg Guaifenesin and 120mg Dextromethorphan daily

Premier Value
CHEST CONGESTION AND COUGH RELIEF
COUGH SUPPRESSANT AND COUGH RELIEF
Dextromethorphan HBr 20mg
EXPECTORANT
400mg Guaifenesin

- Immediate Release Caplets
- Loosens & Relieves Chest Congestion
- Makes Coughs More Productive
- Controls Cough
- Dye-free

50 Caplets
Provides up to 2400mg Guaifenesin and 120mg Dextromethorphan daily

2

Enter section text here

PREMIER VALUE CHEST CONGESTION AND COUGH RELIEF DM
dextromethorphan hydrobromide / guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10956-020
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE, COLLOIDAL (UNII: ETJ7Z6XBU4)	
COPOVIDONE (UNII: D9C330MD8B)	
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:10956-020-01	1 in 1 CARTON		
1	NDC:10956-020-11	50 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/30/2009	

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

Name	Address	ID/FEI	Business Operations
-------------	----------------	---------------	----------------------------

Reese Pharmaceutical Co		004172052	relabel, repack
-------------------------	--	-----------	-----------------

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture

Revised: 10/2010

Reese Pharmaceutical Co