

**FREDS CHEST CONGESTION RELIEF 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) (MAOI)

Certain drugs for depression, psychiatric or emotional conditions or Parkinson's disease

or for 2 weeks after stopping MAOI drug, If you do not know if your prescription drug contains
an MAOI, 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



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FREDS CHEST CONGESTION RELIEF DM

dextromethorphan hydrobromide / guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10956-761
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

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:10956-761-01	1 in 1 CARTON		
1	NDC:10956-761-50	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: 7/2010

Reese Pharmaceutical Co