ROBAFEN DM- dextromethorphan hydrobromide, guaifenesin solution Major Pharmaceuticals

Major Pharmaceuticals Robafen® DM Drug Facts

Active ingredients (in each 20 mL)

Dextromethorphan HBr, USP 20 mg Guaifenesin, USP 200 mg

Purposes

Cough suppressant Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

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 that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if

cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. 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 right away (1-800-222-1222).

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- this adult product is not intended for use in children under 12 years of age

age	dose		
adults and children 12 years and over	20 mL every 4 hours		
children under 12 years	do not use		

Other information

- each 20 mL contains: sodium 14 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, FD&C red no. 40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-616-2471

Package/Label Principal Display Panel

MAJOR®

Compare to Robitussin[®] Cough + Chest Congestion DM active ingredients

Robafen[®] DM Cough and Chest Congestion

Dextromethorphan HBr, USP 20 mg

Guaifenesin, USP 200 mg

Cough Suppressant

Expectorant

Controls Cough

Relieves Chest Congestion

Thins and Loosens Mucus

SEE NEW DOSING

Raspberry Flavor

Non-Drowsy

For Adults Ages 12 and Over

4 FL. OZ. (118 mL)



ROBAFEN DM									
dextromethorphan hydrobromide, guaifenesin solution									
Ρ	roduct Infor	mation							
Р	roduct Type		HUMAN OTC DRUG	Ite	Item Code (Source) ND			DC:0904-7223	
		istration	ORAL						
		ute of Administration ORAL							
Active Ingredient/Active Moiety									
	g		-			Basis of Str	onath	Strength	
Ingredient Name DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH (DEXTROMETHORPHAN - UNII:7355X3ROTS)			-19KYH)		DEXTROMETHORPHAN HYDROBROMIDE		20 mg in 20 mL		
GUAIFENESIN (UNII: 495W7451VQ) (GU			(GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN		200 mg in 20 mL		
Inactive Ingredients									
			Ingredient Na	me				Strength	
AN	HYDROUS CITR	IC ACID (UNII: X	F417D3PSL)					-	
FC	&C RED NO. 40	(UNII: WZ B9127	XOA)						
GL	YCERIN (UNII: PE	DC6A3C0OX)							
PR	OPYLENE GLYC	OL (UNII: 6DC9Q	167V3)						
w	ATER (UNII: 059Q	F0KO0R)							
SODIUM BENZOATE (UNII: OJ245FE5EU)									
sc	DIUM CITRATE,	UNSPECIFIED	FORM (UNII: 1Q73Q	2JULR)					
sc	DRBITOL (UNII: 5	06T60A25R)							
รเ	JCRALOSE (UNII:	96K6UQ3ZD4)							
XA	NTHAN GUM (UI	NII: TTV12P4NEE))						
P	roduct Chara	acteristics							
Сс	olor		RED	Score					
Sł	nape			Size					
Flavor		FRUIT	Imprint Code						
Contains			• • • • • • • • • • • • • • • • • • • •						
Pa	ackaging								
#	ltem Code	Pac	ckage Description		Ma	rketing Start Date		eting End Date	
1	NDC:0904-7223- 20	1 in 1 CARTON	in 1 CARTON		01/07	/2022			
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product			ion				
2	NDC:0904-7223- 59	1 in 1 CARTON		01/24/2022					
2		237 mL in 1 BO Product	7 mL in 1 BOTTLE; Type 0: Not a Combination oduct						

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC Monograph Drug	M012	01/07/2022						

Labeler - Major Pharmaceuticals (191427277)

Revised: 11/2024

Major Pharmaceuticals