# ROBAFEN- dextromethorphan hbr, guaifenes in solution Major Pharmaceuticals

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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#### Major Pharmaceuticals Robafen® Drug Facts

#### Active ingredients (in each 10 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	10 mL every 4 hours	
children under 12 years	do not use	

#### Other information

- each 10 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

#### **Inactive ingredients**

anhydrous citric acid, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sucralose

#### Questions or comments?

1-800-616-2471

#### **Principal Display Panel**

**ROBAFEN®** 

**DM COUGH** 

COUGH SUPPRESSANT (Dextromethorphan HBr)

EXPECTORANT (Guaifenesin)

PEAK COLD

Relieves:

Cough

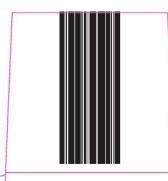
Mucus

Non-Drowsy

COMPARE TO the active ingredients of ROBITUSSIN® COUGH + CHEST CONGESTION DM

FOR ADULTS 12 and Over

8 FL. OZ. (237 mL)



# О № солен MAJOR<sup>®</sup>

MAJOR<sup>®</sup>

**MAJOR**°

COUGH

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PEAK COLD

Relieves: Cough Mucus

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USP 20 mg.........Cough suppressant
Gualfenesin, USP 200 mg......Expectorant

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Questions or comments? 1-800-616-2471

#### **Gluten Free**

\*This product is not manufactured or distributed by Pfizer, distributor of Robitussin® Cough + Chest Congestion DM.

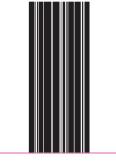
DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

> Distributed by MAJOR® PHARMACEUTICALS 17177 N Laurel Park Dr, Suffe 233 Livonia, MI 48152 USA M-05 REV. 04/18 Re-Order No. 700958

> > Dosage Cup Included



www.StopMedicineAbuse.org





LOT NO.

EXP.

: 35934 5C C5

### ROBAFEN

dextromethorphan hbr, guaifenesin solution

#### **Product Information**

Route of Administration

HUMAN OTC DRUG Product Type Item Code (Source)

ORAL

NDC:0904-6758

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
MENTHOL (UNII: L7T10EIP3A)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Product Characteristics			
Color	RED (clear)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

]	Packaging			
#	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0904-6758-59	1 in 1 CARTON	08/13/2018	
1	l	237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0904-6758-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/13/2018	

## Labeler - Major Pharmaceuticals (191427277)

Revised: 9/2018 Major Pharmaceuticals