

ROBAFEN DM- dextromethorphan hbr, guaifenesin solution
ATLANTIC BIOLOGICALS CORP.

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.

Major Pharmaceuticals Robafen® DM 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

- **Phenylketonurics:Contains Phenylalanine 30 mg per 10 mL**
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

aspartame, benzoic acid, flavor, glycerin, hydroxyethyl cellulose, menthol, polyethylene glycol, purified water

Questions or comments?

1-800-616-2471

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

20101 N/E 16TH PLACE

MIAMI, FL 33179

NDC 17856-6759-01

NDC 17856-6759-01

ROBAFEN DM

**COUGH
SUGAR-FREE
CLEAR**

(Dextromethorphan HBr 20 mg/
Guaifenesin 200 mg per 10 mL)

20 mg / 200 mg per 10 mL

UNIT DOSE 10 mL Cup

COUGH SUPPRESSANT (Dextromethorphan HBr)
EXPECTORANT (Guaifenesin)

Relieves:

Coughs
Chest Congestion
Non-Drowsy

Specially Formulated For **DIABETICS**

FOR ADULTS AGES 12 AND OVER

COMPARE TO the active ingredients of ROBITUSSIN® SUGAR-FREE COUGH+ CONGESTION DM*

PACKAGING INFORMATION:

Dosage per cup: 10 mL

Cup(s) per Case: 72

See package insert for indications and dosage schedule.

Other information:

Store at 20-25°C (68-77°F). Do not refrigerate.

Phenylketonurics: Contains Phenylalanine 30 mg per 10 mL

**KEEP ROBAFEN DM AND ALL MEDICINES OUT OF THE
REACH OF CHILDREN.**

Repackaged by: Unit Dose Solutions, Inc., Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
20101 N.E. 16th Place
Miami, FL 33179

*Retain box label and package insert for drug information.

**Questions or Comments:
Call 1-800-509-7592**

UDS Lot No: XXXXXX
MFG Lot No: XXXXXXXX
Exp. Date: XX/XX/XXXX



17856675901

NDC 17856-6756-02

NDC 17856-6759-02

ROBAFEN DM

**COUGH
SUGAR-FREE
CLEAR**

(Dextromethorphan HBr 10 mg/
Guaifenesin 100 mg per 5 mL)

10 mg / 100 mg per 5 mL

UNIT DOSE 5 mL Cup

**COUGH SUPPRESSANT (Dextromethorphan HBr)
EXPECTORANT (Guaifenesin)**

Relieves:

Coughs

Chest Congestion

Non-Drowsy

Specially Formulated For **DIABETICS**

FOR ADULTS AGES 12 AND OVER

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UDS Lot No: XXXXXX

MFG Lot No: XXXXXXXX

Exp. Date: XX/XX/XXXX



17856675902

ROBAFEN DM

dextromethorphan hbr, guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-6759(NDC:0904-6759)
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 in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
MENTHOL (UNII: L7T10EIP3A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-6759-1	72 in 1 BOX, UNIT-DOSE	12/19/2018	
1		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-6759-2	72 in 1 BOX, UNIT-DOSE	12/19/2018	
2		5 mL in 1 CUP, UNIT-DOSE; 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	12/19/2018	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-6759) , repack(17856-6759)

Revised: 12/2018

ATLANTIC BIOLOGICALS CORP.