

ROBAFEN DM COUGH SUGAR FREE CLEAR- guaifenesin and dextromethorphan hydrobromide solution

Atlantic Biologicals Corps

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.

Robafen DM Cough Sugar Free Clear®

(in each TSP (5 mL)) Active ingredients	Purpose
Dextromethorphan HBr USP 10 mg	Cough suppressant
Guaifenesin USP 100 mg	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

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinsons disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains MAOI, ask a doctor or pharmacist before taking this product. **Do not use:**

Ask a doctor before use if you have

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

Stop use and ask a doctor if

Cough lasts more than 7 days, comes back or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

ask a health professional before use. **If pregnant or breast feeding:**

In case of overdose , get medical help or contact a Poison Control center right away. **Keep out of reach of children.**

Directions

Do not take more than 6 doses in any 24 hour period.

age	dose
Adults and children 12 years and over	2 TSP (teaspoonful) every 4 hours
children under 12 years	do not use

Other information

- sodium- 2mg **Each TSP (5ml) contains:**
- Store at 20-25° C (68-77° F)
- Dosage cup provided

Inactive ingredients

artificial flavor, citric acid, glycerin, menthol, polyethylene glycol 1450, povidone, propylene glycol, purified water, sodium benzoate, sucralose.

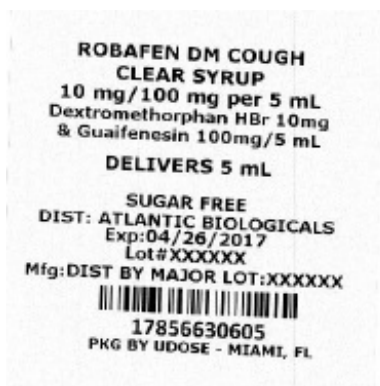
Questions or Comments?

1-800-616-2471

Distributed by: 31778 Enterprise Drive Livonia, MI 48150 USA

MAJOR PHARMACEUTICALS®

ROBAFEN DM COUGH SUGAR FREE CLEAR (GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE) SOLUTION



ROBAFEN DM COUGH SUGAR FREE CLEAR

guaifenesin and dextromethorphan hydrobromide solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-6306(NDC:0904-6306)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Benzoate (UNII: OJ245FE5EU)	
Polyethylene Glycols (UNII: 3WJQ0SDW1A)	
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Glycerin (UNII: PDC6A3C0OX)	

Propylene glycol (UNII: 6DC9Q167V3)	
Povidones (UNII: FZ989GH94E)	
Menthol (UNII: L7T10EIP3A)	
Prunus Serotina Bark (UNII: 5D48E975HA)	
Sucralose (UNII: 96K6UQ3ZD4)	
Water (UNII: 059QF0KO0R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-6306-5	5 mL in 1 CUP; Type 0: Not a Combination Product	05/05/2015	
2	NDC:17856-6306-1	10 mL in 1 CUP; Type 0: Not a Combination Product	05/05/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/20/2012	

Labeler - Atlantic Biologicals Corps (047437707)

Registrant - Atlantic Biologicals Corps (047437707)

Establishment			
Name	Address	ID/FEI	Business Operations
Atlantic Biologicals Corps		047437707	RELABEL(17856-6306) , REPACK(17856-6306)