RABOFEN DM- guaifenesin and dextromethorphan hydrobromide solution
NuCare Pharmaceuticals,Inc.

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.

Rabofen™ DM

Drug Facts

Active ingredients (in each 2 TSP (10 mL))	***Purposes***
Dextromethorphan HBr, USP 20 mg	Cough suppressant
Guaifenesin, USP 200 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

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 lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that 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.

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

- do not take more than 6 doses in any 24-hour period
- use enclosed dosing cup only. Do not use any other device.

- this adult product is not intended for use in children under 12 years of age
- TSP=teaspoonful

adults and children 12 years and over	2 TSP every 4 hours
children under 12 years	do not use

Other information

- each TSP (5 mL) contains: **sodium 3 mg**
- store at 20°-25°C (68°-77°F). Do not refrigerate

TAMPER-EVIDENT

Do not use this product if inner foil seal over the mouth of the bottle is cut, torn, broken or missing

Inactive ingredients

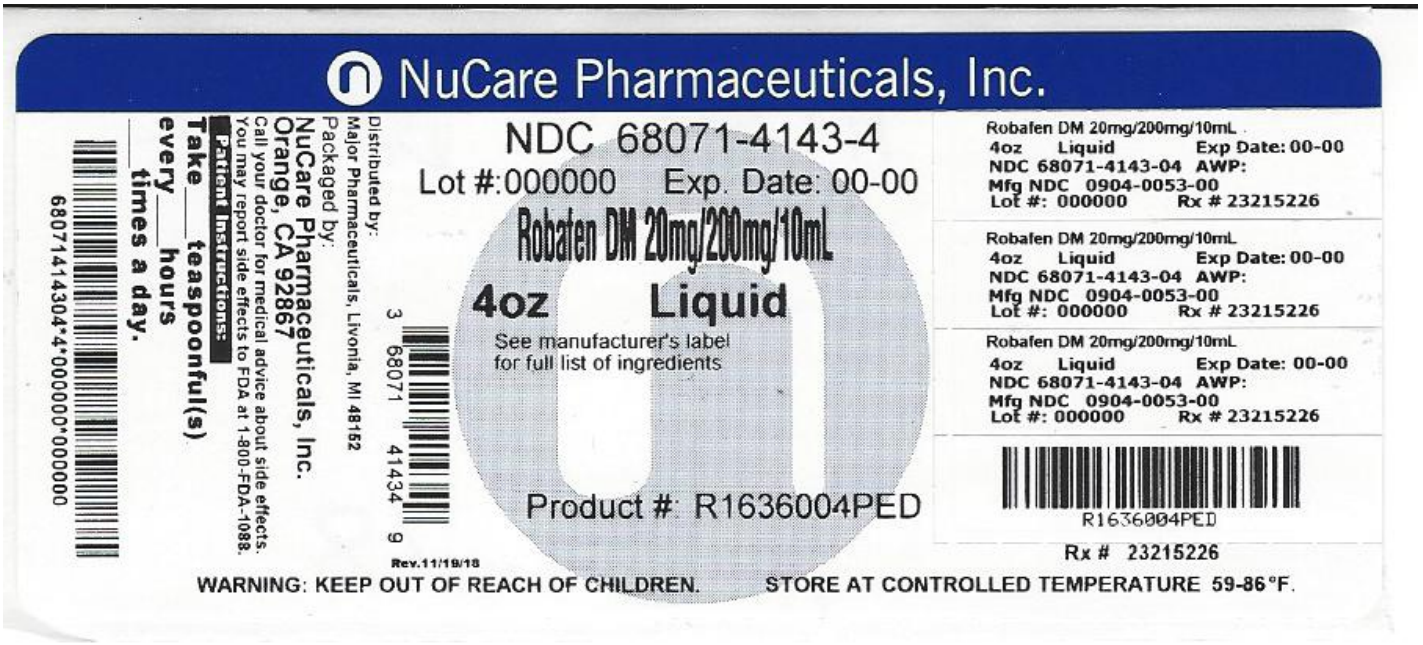
artificial cherry flavor, citric acid, corn syrup, FD&C Red #40, glycerin, menthol, purified water, saccharin sodium, sodium benzoate

Questions or comments?

(800)-616-2471

Distributed by:
MAJOR ® PHARMACEUTICALS
17177 N Laurel Park Drive,
Suite 233, Livonia, MI 48152

PRINCIPAL DISPLAY PANEL -



RABOFEN DM

guaifenesin and dextromethorphan hydrobromide solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-4143(NDC:0904-0053)
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)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
CORN SYRUP (UNII: 9G5L16BK6N)	
PRUNUS SEROTINA BARK (UNII: 5D48E975HA)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics			
Color	red (Reddish-Pink)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4143-4	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2004	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4143)

Revised: 5/2021 NuCare Pharmaceuticals,Inc.