### ROBITUSSIN HONEY MAXIMUM STRENGTH COUGH AND CHEST CONGESTION DM-dextromethorphan hbr, guaifenes in solution Wyeth Consumer Healthcare LLC

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.

-----

### $\textbf{Robitussin}^{\$} \ \textbf{Honey Maximum Strength Cough and Chest Congestion DM}$

### **Drug Facts**

Active ingredients (in each 20 ml)	Purposes
Dextromethorphan HBr, USP 20 mg	Cough suppressant
Guaifenesin, USP 400 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 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 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 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
- 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 21 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

### **Inactive ingredients**

anhydrous citric acid, carboxymethylcellulose sodium, glycerin, natural and artificial flavors, natural grade A honey, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium gluconate, sucralose, xanthan gum, zinc gluconate

### Questions or comments?

call weekdays from 9 AM to 5 PM EST at 1-800-762-4675

Distributed by: Pfizer, Madison, NJ 07940 USA

### PRINCIPAL DISPLAY PANEL - 118 ml Bottle Label

**ADULT** 

Robitussin<sup>®</sup>

Honey

**MAXIMUM STRENGTH** 

Cough+Chest Congestion DM

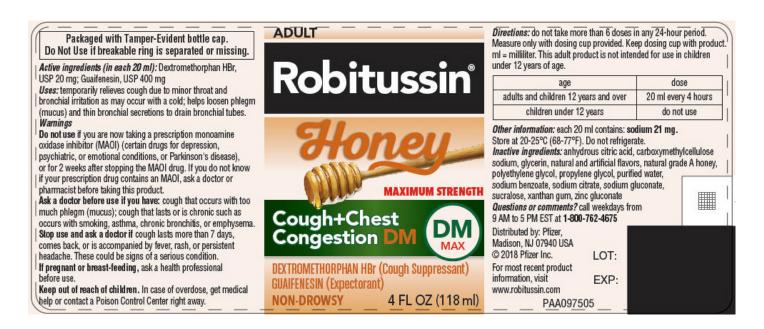
DM

MAX

DEXTROMETHORPHAN HBr (Cough Suppressant) GUAIFENESIN (Expectorant)

**NON-DROWSY** 

4 FL OZ (118 ml)



### PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

NEW!

Robitussin<sup>®</sup>

Honey

Cough+Chest Congestion DM

DEXTROMETHORPHAN HBr (Cough Suppressant) GUAIFENESIN (Expectorant)

**NON-DROWSY** 

### MAXIMUM STRENGTH

- Controls Cough
- Relieves Chest Congestion
- Thins & Loosens Mucus

Taste the Real Honey

DM MAX

For Ages 12+ 4 FL OZ (118 ml)





**ADULT** 

NEW!

**ADULT** 

## Robitussin Robitussin



# Cough+Chest Congestion DM

DEXTROMETHORPHAN HBr (Cough Suppressant)
GUAIFENESIN (Expectorant)

ON-DROWSY

### **MAXIMUM STRENGTH**

- ✓ Controls Cough
- ✓ Relieves Chest Congestion
- ✓ Thins & Loosens Mucus







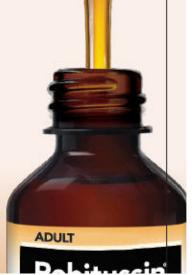


This new dynamic duo combines the great taste of natural honey you want with the powerful, effective cough relief you need.











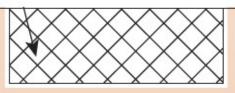






3 0031 8756 12 6

LOT: EXP: CODING AREA (UNVARNISHED)



Packaged with Tamper-Evident bottle cap.

Do Not Use if breakable ring is separated or missing.

### **ADULT**

### Robitussin



Cough+Chest Congestion DM

### Drug Facts

Active ingredients (in each 20 ml)

Dextromethorphan HBr, USP 20 mg...Cough suppressant Gualfenesin, USP 400 mg.....Expectorant

Purposes

### Drug Facts (continued)

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 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
- 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

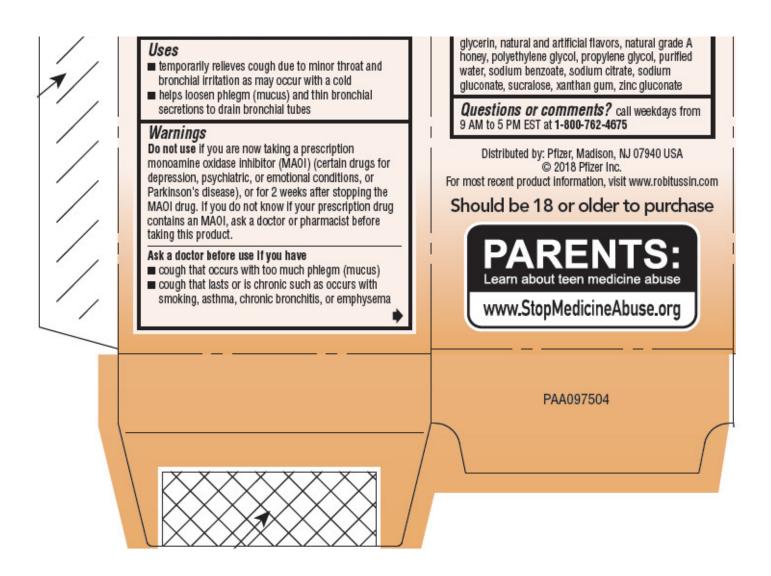
age	dose	
adults and children 12 years and over	20 ml every 4 hours	
children under 12 years	do not use	

### Other information

- each 20 ml contains: sodium 21 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

### Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium,



### ROBITUSSIN HONEY MAXIMUM STRENGTH COUGH AND CHEST CONGESTION DM

dextromethorphan hbr, guaifenesin solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8756	
Route of Administration	ORAL			

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 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)		

GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ZINC GLUCONATE (UNII: U6 WSN5SQ1Z)	
HO NEY (UNII: Y9 H1V576 FH)	

]	Packaging				
#	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:0031-8756-12	1 in 1 CARTON	06/25/2018		
1	l	118 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:0031-8756-18	1 in 1 CARTON	06/25/2018		
2	2	237 mL in 1 BOTTLE; 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	06/25/2018	

### Labeler - Wyeth Consumer Healthcare LLC (828831730)

Establishment			
Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8756), LABEL(0031-8756), MANUFACTURE(0031-8756), PACK(0031-8756)

Revised: 10/2019 Wyeth Consumer Healthcare LLC