

**CHILDRENS ROBITUSSIN HONEY COUGH AND CHEST CONGESTION DM-  
dextromethorphan hbr, guaifenesin solution**

**Richmond Division of Wyeth**

*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.*

-----

**Children's Robitussin® Honey Cough and Chest Congestion DM**

***Drug Facts***

<b><i>Active ingredients (in each 10 ml)</i></b>	<b><i>Purposes</i></b>
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***

**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

<b>age</b>	<b>dose</b>
children under 4 years	do not use
children 4 to under 6 years	5 ml every 4 hours
children 6 to under 12 years	10 ml every 4 hours
adults and children 12 years and over	20 ml every 4 hours

### Other information

- each 10 ml contains: **sodium 11 mg**
- store at 20-25°C (68-77°F). Do not refrigerate.

### Inactive ingredients

anhydrous citric acid, blueberry juice concentrate, carboxymethylcellulose sodium, glycerin, lactic acid, 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

Children's  
Robitussin®

Honey

For Ages 4+

Cough & Chest  
Congestion

DM

DEXTROMETHORPHAN HBr (Cough Suppressant)  
GUAIFENESIN (Expectorant)

NON-DROWSY

4 FL OZ (118 ml)

**Packaged with Tamper-Evident bottle cap.  
Do Not Use if breakable ring is separated or missing.**

**Active ingredients (in each 10 ml):** Dextromethorphan HBr, USP 10 mg; Guaifenesin, USP 100 mg

**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.

**Children's**  
**Robitussin®**  
**Honey**  
**For Ages 4+**  
**Cough & Chest Congestion** **DM**  
**DEXTROMETHORPHAN HBr (Cough Suppressant)**  
**GUAIFENESIN (Expectorant)**  
**NON-DROWSY** 4 FL OZ (118 ml)

**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.

age	dose
children under 4 years	do not use
children 4 to under 6 years	5 ml every 4 hours
children 6 to under 12 years	10 ml every 4 hours
adults and children 12 years and over	20 ml every 4 hours

**Other information:** each 10 ml contains: sodium 11 mg.  
Store at 20-25°C (68-77°F). Do not refrigerate.  
**Inactive ingredients:** anhydrous citric acid, blueberry juice concentrate, carboxymethylcellulose sodium, glycerin, lactic acid, 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  
© 2018 Pfizer Inc. LOT: \_\_\_\_\_  
For most recent product information, visit [www.robitussin.com](http://www.robitussin.com) EXP: \_\_\_\_\_  
PAA097541

### PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

Children's

NEW!

Robitussin®

Honey

For Ages 4+

Cough & Chest

Congestion

DM

DEXTROMETHORPHAN HBr

(Cough Suppressant)

GUAIFENESIN (Expectorant)

NON-DROWSY

Relieves:

□ Chest congestion

□ Mucus

□ Cough

Taste the

Real Honey

TRUE

SOURCE

CERTIFIED

HONEY□

4 FL OZ (118 ml)

Children's

**Robitussin**



Cough & Chest  
Congestion

DM

Children's

NEW!

Children's

**Robitussin® Robitussin®**



For Ages 4+

Cough & Chest  
Congestion

DM

DEXTROMETHORPHAN HBr  
(Cough Suppressant)  
GUAIFENESIN (Expectorant)

NON-  
DROWSY

Relieves:

- ✓ Chest congestion
- ✓ Mucus
- ✓ Cough

Taste the  
Real Honey



4 FL OZ (118 ml)



*Honey*

This new dynamic duo  
combines the great taste  
of natural honey with  
the effective cough relief  
of Robitussin® you trust  
to help your child feel better.

Made  
with  
**Real  
Honey**




Gluten Free

No Artificial  
Colors





85% FPO



3 0031 8760 12 3

DATE & LOT CODING AREA (UNVARNISHED)

LOT:  
EXP:

Do Not Use if breakable ring is separated or missing.  
Packaged with Tamper-Evident bottle cap.

Children's

**Robitussin<sup>®</sup>**



**Drug Facts**

Active ingredients (in each 10 ml)	Purposes
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**

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

**Drug Facts (continued)**

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

age	dose
children under 4 years	do not use
children 4 to under 6 years	5 ml every 4 hours
children 6 to under 12 years	10 ml every 4 hours
adults and children 12 years and over	20 ml every 4 hours

**Other information**

- each 10 ml contains: sodium 11 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients**

anhydrous citric acid, blueberry juice concentrate, carboxymethylcellulose sodium, glycerin, lactic acid, 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

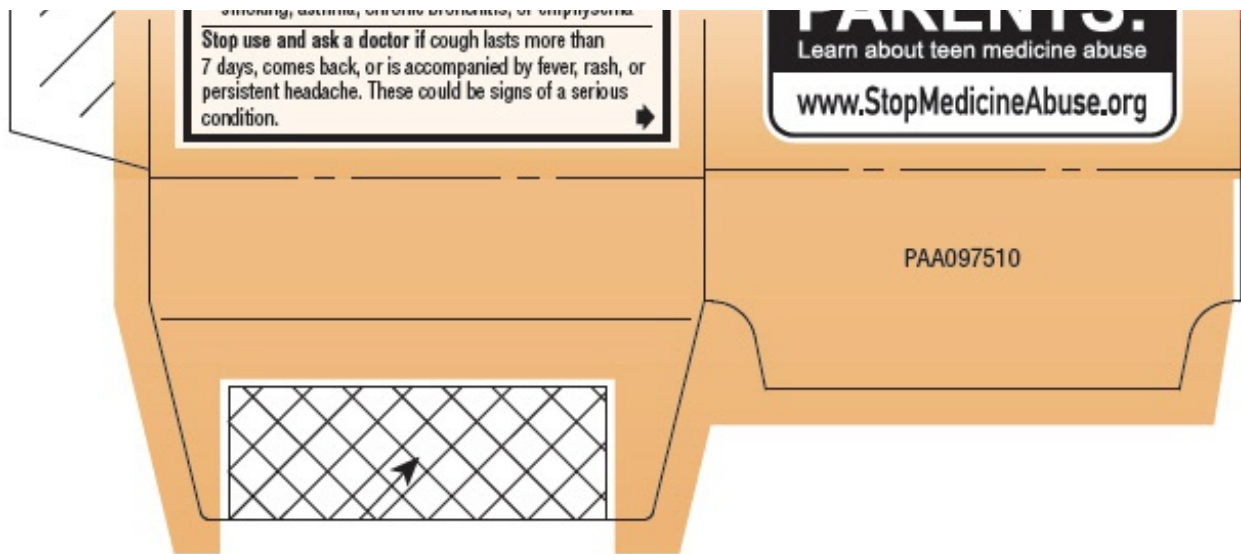
**Questions or comments?** call weekdays from 9 AM to 5 PM EST at 1-800-762-4675

Distributed by: Pfizer, Madison, NJ 07940 USA  
© 2018 Pfizer Inc.

For most recent product information, visit [www.robitussin.com](http://www.robitussin.com)

Should be 18 or older to purchase

**PARENTS.**



## CHILDRENS ROBITUSSIN HONEY COUGH AND CHEST CONGESTION DM

dextromethorphan hbr, guaifenesin solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0031-8760
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT)	
<b>HONEY</b> (UNII: Y9H1V576FH)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>ZINC GLUCONATE</b> (UNII: U6WSN5SQ1Z)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8760-12	1 in 1 CARTON	06/25/2018	
1		118 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** - Richmond Division of Wyeth (829390835)

## Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8760) , LABEL(0031-8760) , MANUFACTURE(0031-8760) , PACK(0031-8760)

Revised: 5/2019

Richmond Division of Wyeth