ROBITUSSIN HONEY MAXIMUM STRENGTH NIGHTTIME COUGH DM-
dextromethorphan hbr, doxylamine succinate 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.

Robitussin® Honey Maximum Strength Nighttime Cough DM

Drug Facts

Active ingredients (in each 20 ml)	***Purposes***
Dextromethorphan HBr, USP 30 mg	Cough suppressant
Doxylamine Succinate, USP 12.5 mg	Antihistamine

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
- controls the impulse to cough to help you sleep

Warnings

Do not use

- to sedate a child or to make a child sleepy
- 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

- trouble urinating due to an enlarged prostate gland
- glaucoma
- a cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness

- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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

- measure only with dosing cup provided
- keep dosing cup with product
- ml = milliliter
- do not take more than 4 doses in any 24-hour period
- 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 6 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)

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

ADULT

Robitussin®

Honey

MAXIMUM STRENGTH

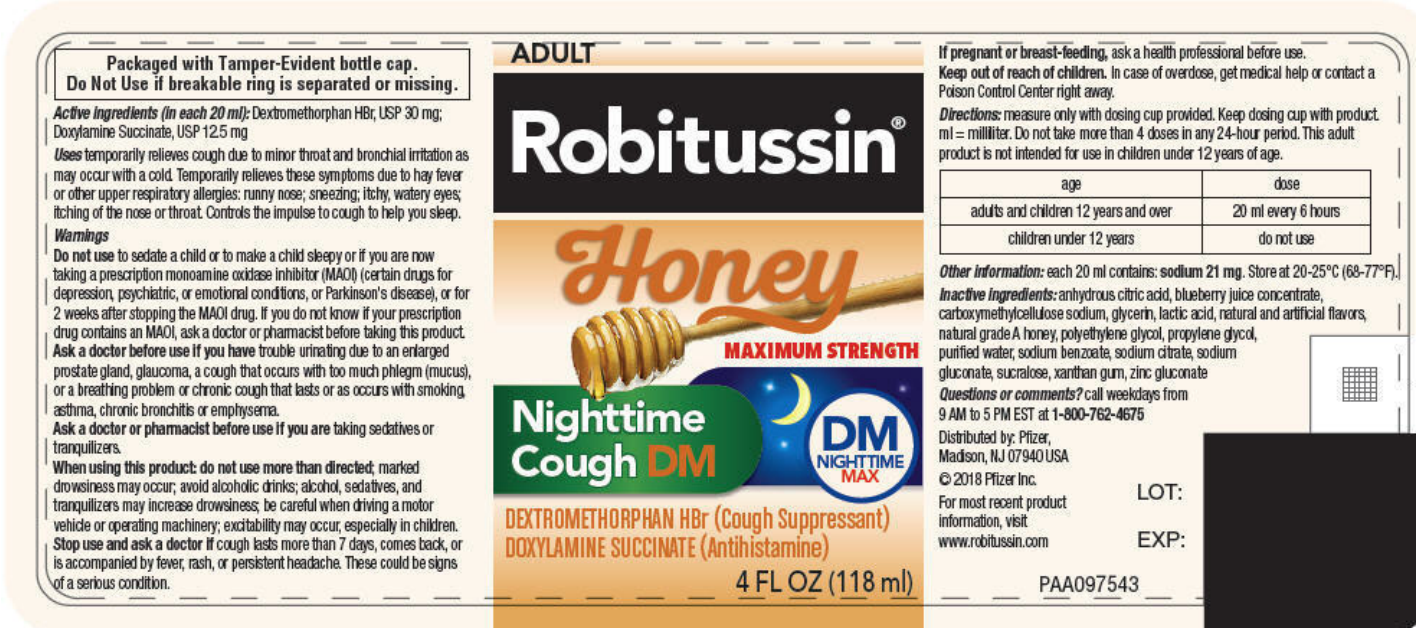
Nighttime
Cough DM

DM
NIGHTTIME

MAX

DEXTROMETHORPHAN HBr (Cough Suppressant)
DOXYLAMINE SUCCINATE (Antihistamine)

4 FL OZ (118 ml)



PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

ADULT

NEW!

Robitussin®

Honey

Nighttime
Cough DM

DEXTROMETHORPHAN HBr (Cough Suppressant)
DOXYLAMINE SUCCINATE (Antihistamine)

MAXIMUM STRENGTH

- Controls Cough
- Relieves runny nose and sneezing

Taste the
Real Honey

DM
NIGHTTIME
MAX

For Ages 12+
4 FL OZ (118 ml)

ADULT

Robitussin

Honey

MAXIMUM STRENGTH

Nighttime Cough DM

DM NIGHTTIME MAX

ADULT

NEW!

ADULT

Robitussin® Robitussin®

Honey

Nighttime Cough DM

DEXTROMETHORPHAN HBr (Cough Suppressant)
DOXYLAMINE SUCCINATE (Antihistamine)

MAXIMUM STRENGTH

- ✓ Controls Cough
- ✓ Relieves runny nose and sneezing

Taste the Real Honey

DM NIGHTTIME MAX

For Ages 12+

Honey

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

Made with *Real* HONEY

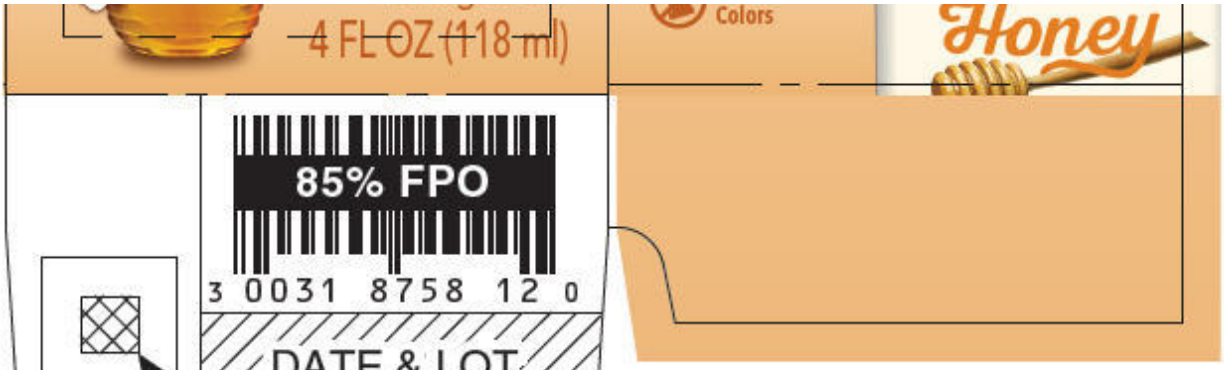
TRUE SOURCE CERTIFIED HONEY

Gluten Free

No Artificial

ADULT

Robitussin



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

Robitussin®

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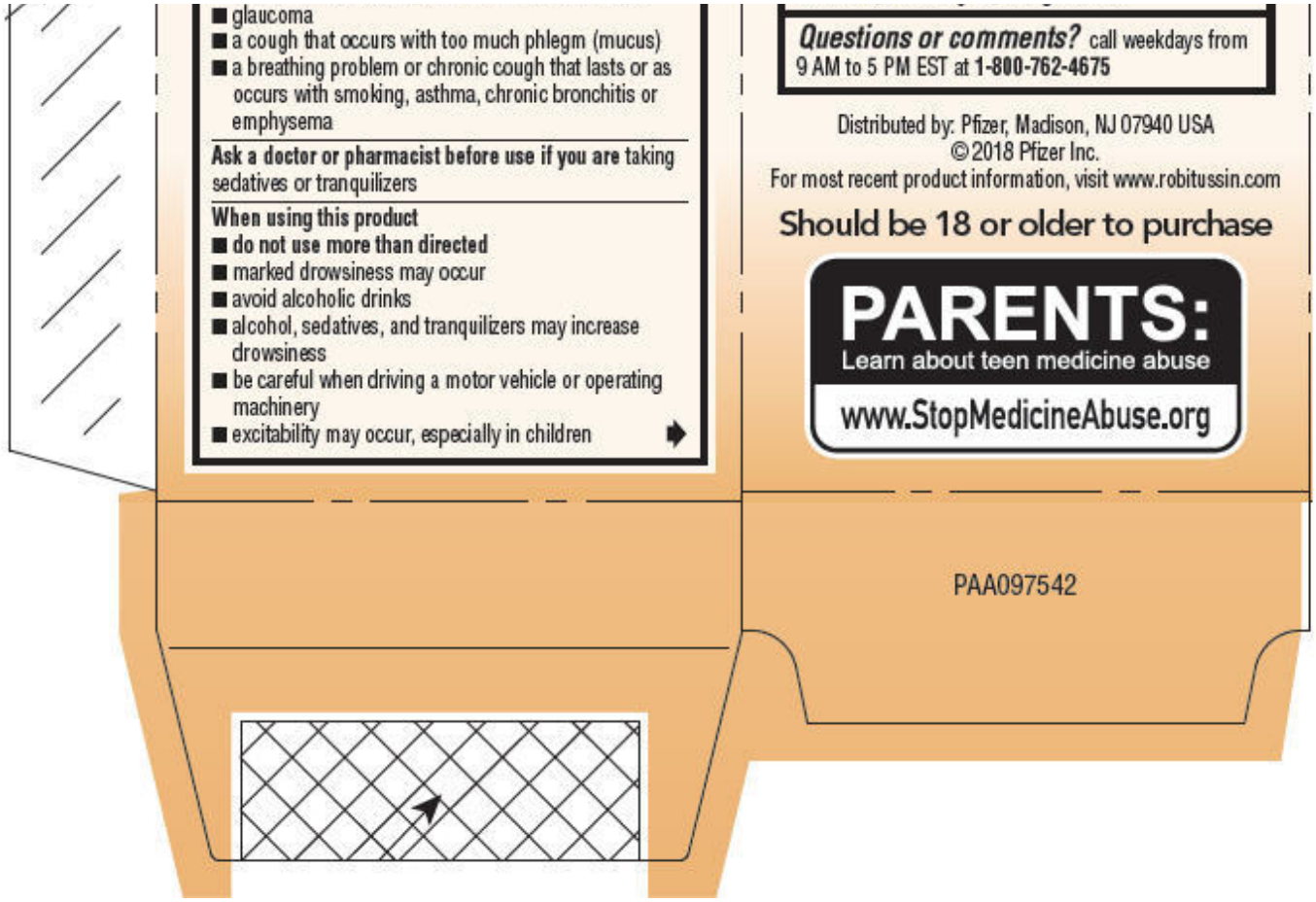

ROBITUSSIN HONEY MAXIMUM STRENGTH NIGHTTIME COUGH DM

dextromethorphan hbr, doxylamine succinate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8758
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 20 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
HONEY (UNII: Y9H1V576FH)	
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: U6WSN5SQ1Z)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8758-12	1 in 1 CARTON	06/25/2018	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8758-18	1 in 1 CARTON	06/25/2018	
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 - Richmond Division of Wyeth (829390835)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8758) , LABEL(0031-8758) , MANUFACTURE(0031-8758) , PACK(0031-8758)

Revised: 6/2019 Richmond Division of Wyeth