ROBITUSSIN MAXIMUM STRENGTH NIGHTTIME COUGH DM- dextromethorphan hydrobromide, 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® 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 14 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, FD&C blue no. 1, FD&C red no. 40, glycerin, liquid glucose, menthol, natural and artificial flavors, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sucralose, triacetin, xanthan gum

Questions or comments?

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

Made in Canada

For most recent product information, **visit www.robitussin.com**

Distributed by:
Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Label

ADULT

Robitussin®

MAXIMUM STRENGTH

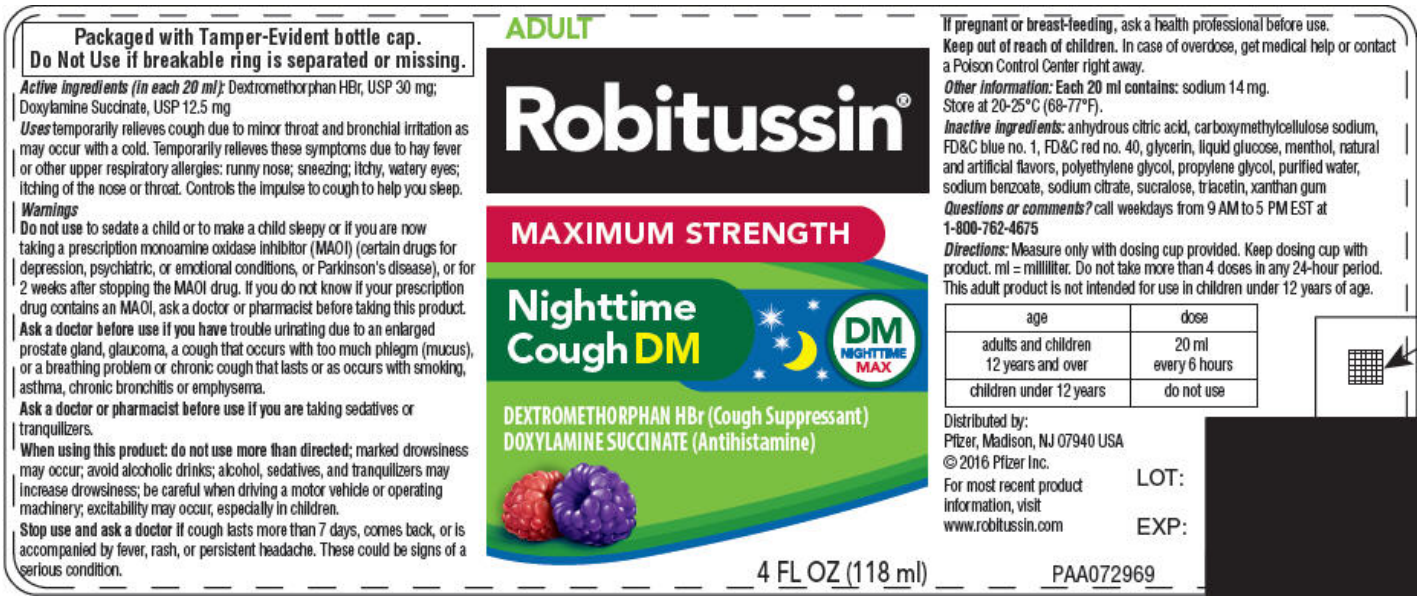
Nighttime
Cough DM

DM
NIGHTTIME
MAX

DEXTROMETHORPHAN HBr (Cough Suppressant)

DOXYLAMINE SUCCINATE (Antihistamine)

4 FL OZ (118 ml)



PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

ADULT

Robitussin®

MAXIMUM STRENGTH

Nighttime
Cough DM

DEXTROMETHORPHAN HBr (Cough Suppressant)
DOXYLAMINE SUCCINATE (Antihistamine)

- Controls Cough
- Relieves Runny Nose & Sneezing

FAST, EFFECTIVE
cough relief

DM
NIGHTTIME
MAX

For Ages 12 & Over
4 FL OZ (118 ml)

ADULT

Robitussin

MAXIMUM STRENGTH

Nighttime Cough DM

DM NIGHTTIME MAX

ADULT

Robitussin® Robitussin®

MAXIMUM STRENGTH

Nighttime Cough DM

DEXTROMETHORPHAN HBr (Cough Suppressant)
DOXYLAMINE SUCCINATE (Antihistamine)

- ✓ Controls Cough
- ✓ Relieves Runny Nose & Sneezing

FAST, EFFECTIVE cough relief

DM NIGHTTIME MAX

STRONG SOOTHING ACTION

and fast, powerful cough relief

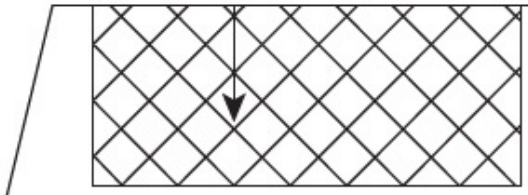
Also available:

Should be 18 or older to purchase

PARENTS:
Learn about teen medicine abuse

For Ages 12 & Over 4 FL OZ (118 ml)

www.StopMedicineAbuse.org



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

ADULT

Robitussin®

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Drug Facts (continued)

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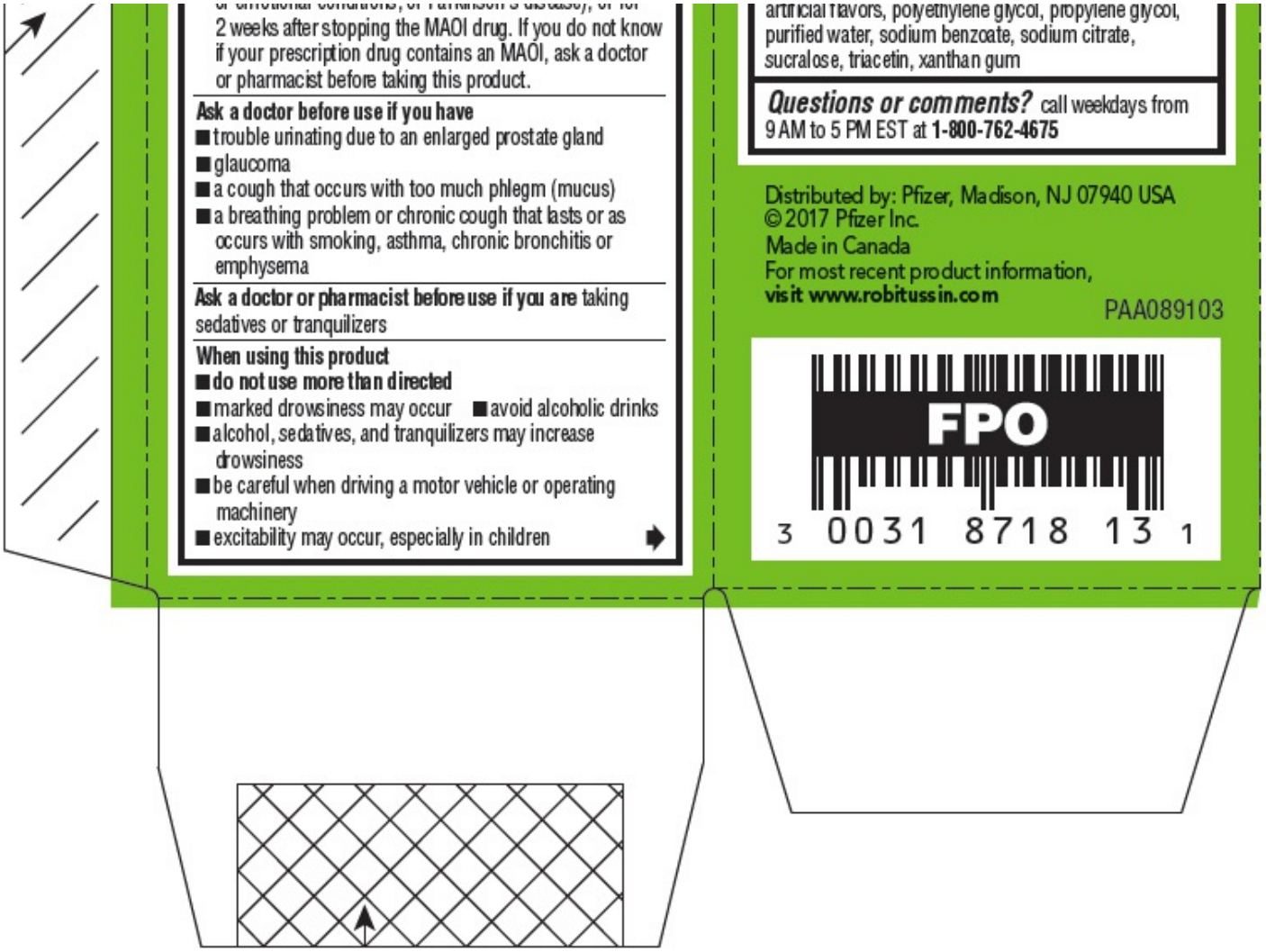

ROBITUSSIN MAXIMUM STRENGTH NIGHTTIME COUGH DM

dextromethorphan hydrobromide, doxylamine succinate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8718
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)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8718-13	1 in 1 CARTON	06/01/2016	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8718-18	1 in 1 CARTON	06/01/2016	
2		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0031-8718-24	1 in 1 CARTON	06/01/2016	
3		355 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	06/01/2016	

Labeler - Richmond Division of Wyeth (829390835)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8718) , LABEL(0031-8718) , MANUFACTURE(0031-8718) , PACK(0031-8718)

Revised: 1/2019 Richmond Division of Wyeth