ROBITUSSIN MAXIMUM STRENGTH COUGH PLUS CHEST CONGESTION DM-
dextromethorphan hydrobromide, guaifenesin 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.

ROBITUSSIN® MAXIMUM STRENGTH COUGH PLUS 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 12 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

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®

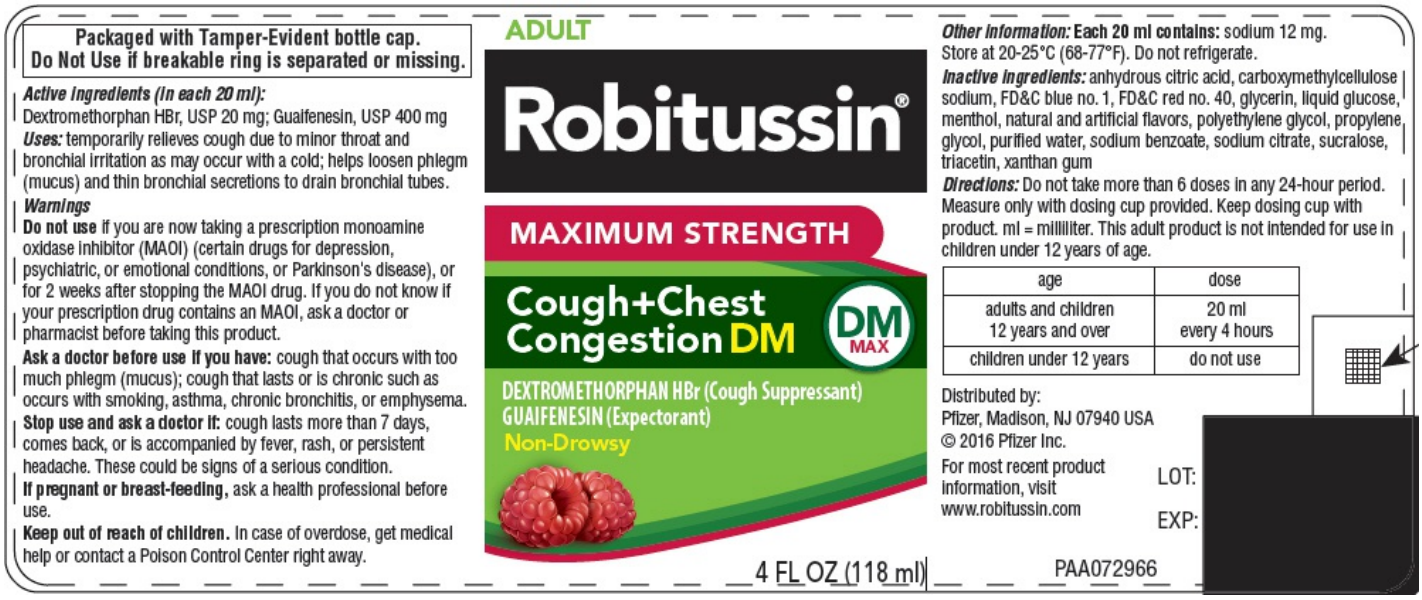
MAXIMUM STRENGTH

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

See
New
Dosing

ADULT
Robitussin®

MAXIMUM STRENGTH

Cough+Chest
Congestion DM

DEXTROMETHORPHAN HBr (Cough Suppressant)
GUAIFENESIN (Expectorant)

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

Non-Drowsy

BETTER
TASTING!
Same Effective
Cough Relief*

DM
MAX

For Ages 12 & Over

4 FL OZ (118 ml)

ADULT

Robitussin

MAXIMUM STRENGTH

Cough+Chest Congestion DM

DM MAX

ADULT

See New Dosing

Robitussin®

Robitussin®

MAXIMUM STRENGTH

Cough+Chest Congestion DM

DEXTROMETHORPHAN HBr (Cough Suppressant)
GUAIFENESIN (Expectorant)

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

Non-Drowsy

BETTER TASTING!
Same Effective Cough Relief*

DM MAX

NOW Better Tasting plus

STRONGER SOOTHING ACTION*

Same Maximum Strength Relief

Should be 18 or older to purchase

PARENTS:
Learn about teen medicine abuse

www.StopMedicineAbuse.org

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

*Compared to Robitussin Cough + Chest Congestion DM Max (10 ml)

FPO

3 0031 8739 12 9

LOT:
EXP:

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

ADULT

Robitussin

MAXIMUM STRENGTH

Cough+Chest Congestion DM

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Warnings

Do not use if you are now taking a prescription

Drug Facts (continued)

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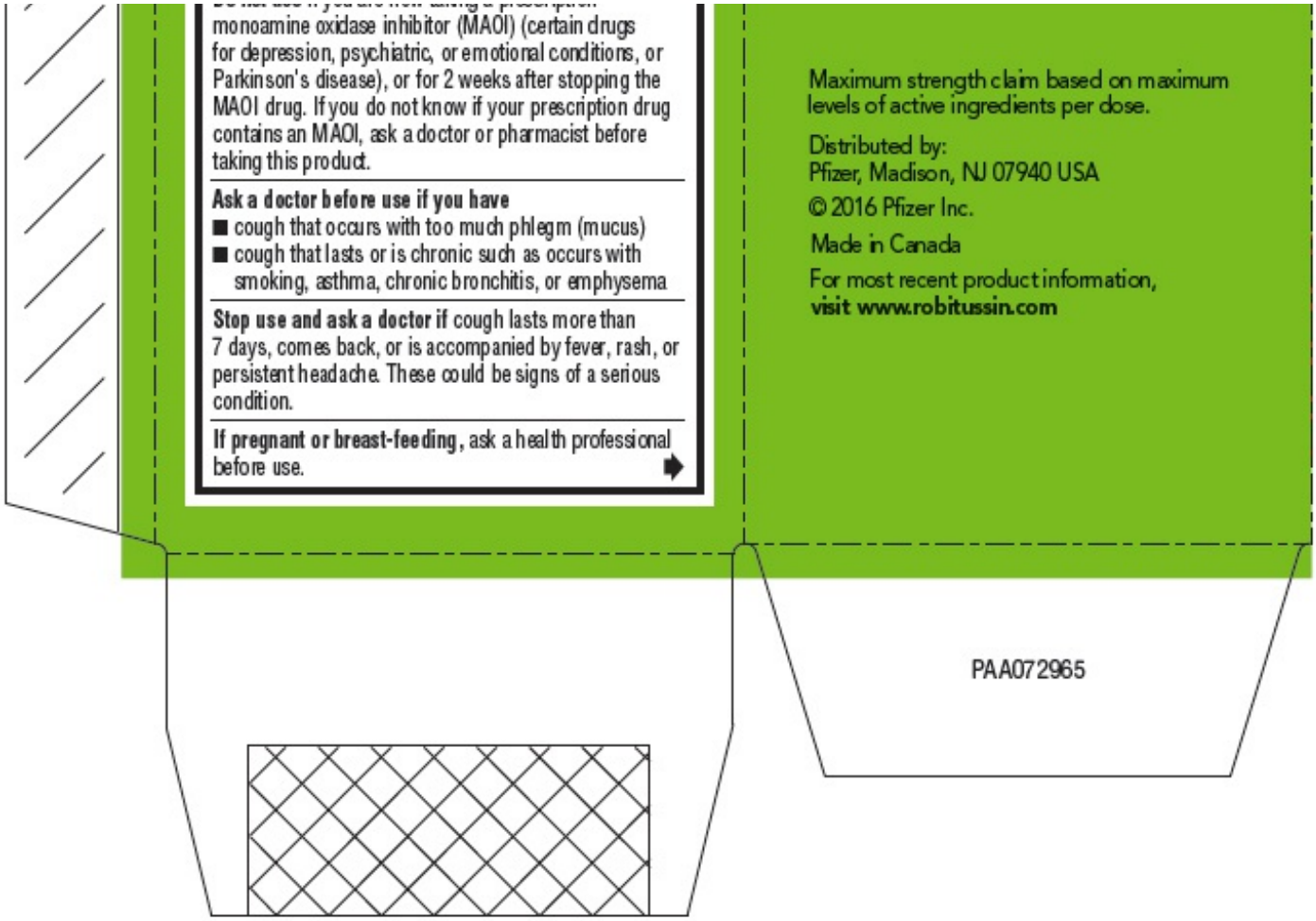

ROBITUSSIN MAXIMUM STRENGTH COUGH PLUS CHEST CONGESTION DM

dextromethorphan hydrobromide, guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8739
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (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**
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		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8739-12	1 in 1 CARTON	06/01/2016	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8739-18	1 in 1 CARTON	06/01/2016	
2		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0031-8739-42	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 - Wyeth Consumer Healthcare LLC (828831730)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8739) , LABEL(0031-8739) , MANUFACTURE(0031-8739) , PACK(0031-8739)

Revised: 10/2019 Wyeth Consumer Healthcare LLC