

**ROBITUSSIN DAY AND NIGHT COUGH RELIEF DM MAX- dextromethorphan hydrobromide, guaifenesin, doxylamine succinate**  
**Haleon US Holdings LLC**

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***Drug Facts***

***Active ingredients (in each 20 mL) - Robitussin Maximum Strength Cough+Chest Congestion DM***

Dextromethorphan HBr, USP 20 mg

Guaifenesin, USP 400 mg

***Purposes - Robitussin Maximum Strength Cough+Chest Congestion DM***

Cough suppressant

Expectorant

***Uses - Robitussin Maximum Strength Cough+Chest Congestion DM***

- 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 - Robitussin Maximum Strength Cough+Chest Congestion DM***

**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.**

***Directions - Robitussin Maximum Strength Cough+Chest Congestion DM***

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 - Robitussin Maximum Strength Cough+Chest Congestion DM***

- **each 20 mL contains:** sodium 13 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

***Inactive ingredients - Robitussin Maximum Strength Cough+Chest Congestion DM***

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? - Robitussin Maximum Strength Cough+Chest Congestion DM***

call weekdays from 8 AM to 6 PM EST at **1-800-245-1040**

***Active ingredients (in each 20 mL) - Robitussin Maximum Strength Nighttime Cough DM***

Dextromethorphan HBr, USP 30 mg

Doxylamine succinate, USP 12.5 mg

***Purposes - Robitussin Maximum Strength Nighttime Cough DM***

Cough suppressant

## Antihistamine

### **Uses - Robitussin Maximum Strength Nighttime Cough DM**

- 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 - Robitussin Maximum Strength Nighttime Cough DM**

#### **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 a 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**

***Directions - Robitussin Maximum Strength Nighttime Cough DM***

- 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 - Robitussin Maximum Strength Nighttime Cough DM***

- **each 20 mL contains:** sodium 14 mg
- store at 20-25°C (68-77°F)

***Inactive ingredients - Robitussin Maximum Strength Nighttime Cough DM***

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? - Robitussin Maximum Strength Nighttime Cough DM***

call weekdays from 9 AM to 5 PM EST at **1-800-245-1040**

***Additional information - Robitussin Maximum Strength Day/Night Combination Package***

**TAMPER-EVIDENT INNER UNITS:**

**Do Not Use if Tamper-Evident feature on either bottle cap is broken or missing. See individual inner cartons and bottle labels for specific Tamper-Evident features.**

4 oz 8 oz **Maximum Strength Cough+Chest Congestion DM**

8 oz **Maximum Strength Nighttime Cough DM**

**Do not take both products within 6 hours of each other.**

**STRONG SOOTHING ACTION** and fast, powerful cough relief

**PARENTS: Learn about teen medicine abuse**

**[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)**

**Principal Display Panel - Robitussin Maximum Strength Cough+Chest Congestion DM**

ADULT

**Robitussin**

**MAXIMUM STRENGTH**

**Cough+Chest Congestion DM**

DEXTROMETHORPHAN HBr (Cough Suppressant)

GUAIFENESIN (Expectorant)

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

**FAST, EFFECTIVE** cough relief

**DM MAX**

For Ages 12 & Over

4 FL OZ (118 mL)

ADULT

# Robitussin

**MAXIMUM STRENGTH**

**Cough+Chest  
Congestion **DM****

DEXTROMETHORPHAN HBr (Cough Suppressant)  
GUAIFENESIN (Expectorant)

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



**FAST, EFFECTIVE**  
cough relief

**DM**  
**MAX**

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

**Principal Display Panel - Robitussin Maximum Strength Nighttime Cough DM**

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

8 FL OZ (237 mL)

ADULT

HALEON

# 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 **8 FL OZ (237 mL)**

## **Principal Display Panel - Robitussin Maximum Strength Day/Night Combination Package**

### **DAY&NIGHT COUGH RELIEF**

**DM** MAX

ADULT

INCLUDES TWO 8oz AND ONE 4oz

Robitussin

MAXIMUM STRENGTH

### **COUGH+CHEST CONGESTION DM**

DEXTROMETHORPHAN HBr (Cough Suppressant)

GUAIFENESIN (Expectorant)

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

**FAST, EFFECTIVE** cough relief

**DM** MAX

### **2 BOTTLES**

1-8 FL OZ (237 mL) / 1-4 FL OZ (118 mL)

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

### **1 BOTTLE**

8 FL OZ (237 mL)

For Ages 12 & Over

3 BOTTLES - 20 FL OZ (591 mL) TOTAL



# DAY & NIGHT

COUGH RELIEF




ADULT

INCLUDES TWO 8oz AND ONE 4oz

## Robitussin

HALEON

**MAXIMUM STRENGTH**

### Cough+Chest Congestion DM

DEXTROMETHORPHAN HBr (Cough Suppressant)  
GUAIFENESIN (Expectorant)

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



**FAST, EFFECTIVE**  
cough relief



**2 BOTTLES**  
1-8 FL OZ (237 mL) / 1-4 FL OZ (118 mL)

**MAXIMUM STRENGTH**

### Nighttime Cough DM

DEXTROMETHORPHAN HBr (Cough Suppressant)  
DOXYLAMINE SUCCINATE (Antihistamine)

- ✓ Controls Cough
- ✓ Relieves Runny Nose & Sneezing



**FAST, EFFECTIVE**  
cough relief



**1 BOTTLE**  
8 FL OZ (237 mL)

For Ages 12 & Over

**3 BOTTLES – 20 FL OZ (591 mL) TOTAL**

## ROBITUSSIN DAY AND NIGHT COUGH RELIEF DM MAX

dextromethorphan hydrobromide, guaifenesin, doxylamine succinate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0031-2834
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-2834-01	1 in 1 CARTON; Type 0: Not a Combination Product	03/01/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 BOTTLE	391 mL
Part 2	1 BOTTLE	237 mL

Part 1 of 2

ROBITUSSIN MAXIMUM STRENGTH COUGH PLUS CHEST CONGESTION DM

dextromethorphan hbr, guaifenesin solution

Product Information

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 (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	
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<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8739-12	1 in 1 CARTON		
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:0031-8739-18	1 in 1 CARTON		
2		237 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2016	

### Part 2 of 2

### ROBITUSSIN MAXIMUM STRENGTH NIGHTTIME COUGH DM

dextromethorphan hydrobromide, doxylamine succinate solution

### Product Information

<b>Item Code (Source)</b>	NDC:0031-8718
<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	30 mg in 20 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 20 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<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>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	RED	<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:0031-8718-18	1 in 1 CARTON		
1		237 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/01/2021	

**Labeler** - Haleon US Holdings LLC (079944263)