

**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.**

In case of overdose, get medical help or contact a Poison Control Center right away.

**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.**

In case of overdose, get medical help or contact a Poison Control Center right away.

**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

**DMMAX**

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*

**DMNIGHTTIME 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**

**DMMAX**

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

**DMMAX**

### **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

**DMNIGHTTIME 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

<b>ROBITUSSIN DAY AND NIGHT COUGH RELIEF DM MAX</b>				
dextromethorphan hydrobromide, guaifenesin, doxylamine succinate kit				
Product Information				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0031-2834	
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
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 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

Color	red	Score	
Shape		Size	

<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: V9B19B5YI2) (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)