

**BRONCO SILEN-DM- dextromethorphan hydrobromide, guaifenesin solution**  
**Caribe Natural, 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.*

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**BRONCO SILEN-DM**

**Active Ingredients (in each 10mL)**

Dextromethorphan HBr 20 mg  
Guaifenesin 400 mg

**Purpose**

Cough Suppressant  
Expectorant

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation 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 health professional before taking this product.

**Ask a doctor before use if you have**

- cough that occurs with too much phlegm (mucus)
- cough that last 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 accidental overdose, get medical help or contact a Poison Control Center right away.

**Directions:**

<b>age</b>	<b>dose</b>
adults and children 12 years and over	10 ml (2 teaspoonfuls) every 4 hours; not to exceed 6 doses (12 teaspoonfuls) in a 24 hour period. 5 ml (1 teaspoonful)

children 6 to under 12 years	every 4 hours; not to exceed 6 doses (6 teaspoonfuls) in a 24 hour period.
children under 6 years	Ask a doctor

**Other Information**

- Store at room temperature 15° - 30°C (59° - 86°F)

**Inactive ingredients**

Cherry Flavor, Citric Acid, FD&C red no. 40, Hydroxyethyl Cellulose, Menthol, Methylparaben, Polyethylene Glycol, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate and Sucralose

**Questions:**

Contact us Monday to Friday at (305) 256-1469 9:00am - 5:00pm EST.

**Display Label**

NDC 59561-202-04

GERMA

BRONCO-SILEN-DM

COUGH SUPPRESSANT

EXPECTORANT

Sugar FREE

Alcohol FREE

Non-Drowsy

New Improved Taste

Stronger than Leading Brands

Contents: 4 FL. OZ. (118 mL)

Caliente para  
la tos intensa y  
expectorante  
**BRONCO  
SILEN-DM**  
GERMA®

**OUR GUARANTEE** - This product is satisfaction guaranteed or your money back.

**NUESTRA GARANTIA** - Este producto tiene satisfacción garantizada o le devolvemos su dinero

LOT/EXP. DATE

GM NDC 59561-202-04

GERMA®  
**BRONCO  
SILEN-DM**

COUGH SUPPRESSANT  
EXPECTORANT

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*Stronger  
than  
Leading  
Brands*

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**Caliente para  
la tos intensa y  
expectorante**  
*Más fuerte que las  
marcas líderes*

**Intense  
Cough Reliever  
and expectorant**  
*Stronger Than  
Leading Brands*

For lot number and expiration date,  
see carton top.

Code# GER100B Rev.: 11/15

**TAMPER-EVIDENT DISCLOSURE:**  
Do not use this product if aluminum foil over  
bottle opening is torn, broken or missing.

**SUPRESOR DE LA TOS  
EXPECTORANTE**  
**COUGH SUPPRESSANT  
EXPECTORANT**



Manufactured in U.S.A. for:  
**Caribe Natural, LLC.**  
Miami, Florida 33186  
[www.germa.net](http://www.germa.net)

GM NDC 59561-202-04

GERMA®  
**BRONCO  
SILEN-DM**

**SUPRESOR DE LA TOS  
EXPECTORANTE**

- NO Azucar
- NO Alcohol
- NO da sueño
- Nuevo Sabor

*Más fuerte  
que las  
marcas  
líderes*

Contenido: 4 FL. OZ. (118 mL)



RETAIN CARTON FOR FULL PRODUCT INFORMATION

**Drug Facts**

**Active Ingredients (in each 10mL)** Purpose  
Dextromethorphan HBr 20mg ..... Cough Suppressant  
Guaifenesin 400mg ..... Expectorant

**Uses**

- temporarily relieves cough due to mild 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 health professional before taking this product.

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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**

age	dose
adults and children 12 years and over	10 mL (2 teaspoonfuls) every 4 hours; not to exceed 6 doses (12 teaspoonfuls) in a 24 hour period.
children 6 to under 12 years	5 mL (1 teaspoonful) every 4 hours; not to exceed 6 doses (6 teaspoonfuls) in a 24 hour period.
children under 6 years	Ask a doctor

**Other information**

- store at controlled temperature 15°-30°C (59°-86°F)

**Inactive ingredients**

Cherry Flavor, Citric Acid, FD&C red no. 40, Hydroxyethyl Cellulose, Menthol, Methylparaben, Polyethylene Glycol, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate and Sucralose

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**BRONCO SILEN-DM**

dextromethorphan hydrobromide, guaifenesin solution

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59561-202

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYETHYL CELLULOSE (6500 MPAS AT 2%) (UNII: 2Q40985DRM)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	RED (Clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59561-202-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/05/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/05/2015	

**Labeler** - Caribe Natural, LLC (624210480)

**Registrant** - Caribe Natural, LLC (624210480)

