

G-BRONCO-D- guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride suspension
MCLAREN MEDICAL INC

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.

G-BRONCO-D

Drug Facts

<i>Active Ingredients (in each 5mL)</i>	<i>Purpose</i>
Guaifenesin 200 mg	Expectorant
Dextromethorphan 10 mg	Antitussive
Phenylephrine 5 mg	Nasal Decongestant

Uses

- Temporarily relieves cough due to minor throat and bronchial irritations as may occur with the common cold
- For the temporary relief of nasal congestion due to the common cold
- Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

Do not exceed recommended dosage.

If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor.

If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor.

Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.

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.

If pregnant or breast-feeding, ask a health professional before use. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

Keep this and all drugs out of the reach of children.

Directions

- Do not take more than 6 doses in any 24-hour period.

Adults and children 12 years of age and over	2 teaspoons every 4 hours
Children 6 to under 12 years of age	1 teaspoon every 4 hours

Children 2 to under 6 years of age	½ teaspoon every 4 hours
Children under 2 years of age	Consult a physician

Inactive ingredients

Citric acid, flavor, hydroxymethylcellulose, methylparaben, polysorbate, propylene glycol, propylparaben, purified water, sorbitan monooleate, sorbitol and sucralose.

Other information

Store at 20°-25°C (68°-77°F)

Do not refrigerate

PRINCIPAL DISPLAY PANEL - 474 mL Bottle Label

NDC-43913-403-16

G-Bronco-D Suspension

New Formula

Cough Suppressant • Expectorant • Decongestant
Sugar Free • Phenylalanine Free • Alcohol Free

Cherry Flavor

16 FL OZ (474 mL)

Multiple Dose Unit Package

For Dispensing Under Pharmaceutical Supervision Only

McLaren Medical

<p>Drug Facts (continued)</p> <p>Directions • Do not take more than 6 doses in any 24-hour period.</p> <table border="1"> <tr> <td>Adults and children 12 years of age and over</td> <td>2 teaspoons every 4 hours</td> </tr> <tr> <td>Children 6 to under 12 years of age</td> <td>1 teaspoon every 4 hours</td> </tr> <tr> <td>Children 2 to under 6 years of age</td> <td>½ teaspoon every 4 hours</td> </tr> <tr> <td>Children under 2 years of age</td> <td>Consult a physician</td> </tr> </table> <p>Inactive ingredients Citric acid, flavor, hydroxymethylcellulose, methylparaben, polysorbate, propylene glycol, propylparaben, purified water, sorbitan monooleate, sorbitol and sucralose.</p> <p>Other information: Store at 20°-25°C (68°-77°F) Do not refrigerate</p>	Adults and children 12 years of age and over	2 teaspoons every 4 hours	Children 6 to under 12 years of age	1 teaspoon every 4 hours	Children 2 to under 6 years of age	½ teaspoon every 4 hours	Children under 2 years of age	Consult a physician	<p>NDC-43913-403-16</p> <h1>G-Bronco-D</h1> <h2>Suspension</h2> <h3>New Formula</h3> <p>Cough Suppressant • Expectorant • Decongestant Sugar Free • Phenylalanine Free • Alcohol Free</p> <p>Cherry Flavor</p> <p>16 FL OZ (474 mL)</p> <p>Multiple Dose Unit Package For Dispensing Under Pharmaceutical Supervision Only</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients (in each 5mL)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Guaifenesin 200 mg</td> <td>Expectorant</td> </tr> <tr> <td>Dextromethorphan 10 mg</td> <td>Antitussive</td> </tr> <tr> <td>Phenylephrine 5 mg</td> <td>Nasal Decongestant</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> Temporarily relieves cough due to minor throat and bronchial irritations as may occur with the common cold For the temporary relief of nasal congestion due to the common cold Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive <p>Warnings</p> <p>Do not exceed recommended dosage. If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor. If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor. Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor. A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor. Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor. 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. If pregnant or breast-feeding, ask a health professional before use. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. Keep this and all drugs out of the reach of children.</p>	Active Ingredients (in each 5mL)	Purpose	Guaifenesin 200 mg	Expectorant	Dextromethorphan 10 mg	Antitussive	Phenylephrine 5 mg	Nasal Decongestant
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Manufactured in the USA for:
McLaren Medical Inc
4070 Laguna St
Coral Gables, FL 33146

LOT #:
EXP DATE:

G-BRONCO-D

guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43913-403
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43913-403-16	474 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	07/01/2012	

Labeler - MCLAREN MEDICAL INC (013770591)

Revised: 6/2015

MCLAREN MEDICAL INC