

# **DOMETUSS-G- guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet**

## **DOMEL**

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### **DOMETUSS-G**

#### **Drug Facts**

<b><i>Active ingredients (in each tablet)</i></b>		<b><i>Purpose</i></b>
Guaifenesin	200 mg	Expectorant
Dextromethorphan HBr	20 mg	Cough Suppressant
Phenylephrine HCl	10 mg	Nasal Decongestant

#### **Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily reduces cough due to minor throat and bronchial irritation associated with a cold
- calm the cough control center, and relieves coughing.
- Temporarily relief nasal congestion due to the common cold
- hay fever or other upper respiratory allergies
- sinus congestion and pressure

#### **Warnings**

- ***Do not exceed recommended dosage***

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

#### **Do not use**

- if you are now taken a prescription Monoaminoxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions or Parkinson's disease), or for two weeks after stopping the MAOI drug; If you do not know if you are taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product

**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 give 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.

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

- liver disease
- if you are taking the blood thinning drug warfarin.

**Stop using this product and ask a doctor if**

- new symptoms occur
- symptoms do not improve within 7 days or are accompanied by fever.
- pain or fever persists or gets worse. These could be signs of a serious condition

**Keep out of reach of children.**

**If you are pregnant or breast-feeding,** ask a health professional before use.

**Directions**

**Do not take more than 6 doses in any 24 hours period.**

<b>Age</b>	<b>Dose</b>
adults and children 12 years of age and over	1 tablets every 4 hours.
children 6 to 12 years of age	1/2 tablet every 4 hours.
children under 6 years of age	Consult a doctor.

**Other information**

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

**Tamper evident**

Do not use if there is evidence of tampering.

**Inactive ingredients**

Dicalcium phosphate, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, stearic acid, talc.

**Questions or comments?**

Calle de Diego #488  
San Juan P.R. 00924

Phone: 787-767-3246  
For more information visit

[www.domelpharma.com](http://www.domelpharma.com)

**PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label**

NDC 53809-250-01

DOMETUSS-G

DEXTROMETHORPHAN HBr/  
PHENYLEPHRINE HCl / GUAIFENESIN

- Cough Suppressant
- Nasal Decongestant
- Expectorant

100 TABLETS

# DOMETUSS-G

**DEXTROMETHORPHAN HBr/  
PHENYLEPHRINE HCl / GUAIFENESIN**

- Cough Suppressant
- Nasal Decongestant
- Expectorant

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**Warnings:** ■ *Do not exceed recommended dosage*  
If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor.

**Do not use** ■ if you are now taken a prescription Monoaminoxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions or Parkinson's disease), or for two weeks after stopping the MAOI drug; If you do not know if you are taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product →



**100 TABLETS**

**Drug Facts (continued)**

**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 give 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.

**Ask a doctor before use if you have:** ■ liver disease ■ if you are taking the blood thinning drug warfarin.

**Stop using this product and ask a doctor if:** ■ new symptoms occur ■ symptoms do not improve within 7 days or are accompanied by fever, ■ pain or fever persists or get worse. These could be signs of a serious condition

**Keep out of reach of children.**

**If you are pregnant or breast-feeding,** ask a health professional before use.

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**Questions or comments?** Phone: 787-767-3246  
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San Juan PR, 00924 [www.domelpharma.com](http://www.domelpharma.com)

Rev: 06/19

Lot #:

Exp:

## DOMETUSS-G

guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53809-250
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

Product Characteristics			
<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	D2
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53809-250-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2019	
2	NDC:53809-250-04	4 in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M012	11/11/2019	

**Labeler** - DOMEL (808198837)