DOMETUSS-G- acetaminophen, guaifenesin, dextromethrphan hbr, phenylephrine hcl tablet
Domel Laboratories

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.

DOMETUSS-G

Drug Facts
Active ingredients (in each tablet)

Acetaminophen 325 mg

Guaifenesin 100 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCL 5 mg

Purpose

Analgesic, Fever reducer

Expectorant

Cough Suppressant

Nasal Decongestant

Keep out of reach of children.

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Uses

- minor aches and pains associated with headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more produtive
- temporarily reduces cough due to minor throst 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 respiratory allergies
- sinus congestion and pressure

Warniings

- **Do not exceed the recommended dosage**
- If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor.
- **Alcohol Warning**: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers
- **Liver Warning**: This product contains Acetaminophen. Severe liver damage may occur if you or your child take more than 4 does in 24 hours, wich is the maxium daily allowance.
- A persistant cough may be a sign of a serious condition. If cough persists for more than 1 week , tends to recur, or accompanied by fever, rash or persistant headache, consult a doctor.

- Do not give to children under 3 years of age or use for more than10 days unless directed by a physicisn.
- If symptoms do not improve within 7 days or are accompanied by fever, 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
- with any other drug containing acetaminophen (prescription or non-prescription)
- with any other drug containing acetaminophen, ask a doctor or pharmacist
- if you are allergic to acetaminophen or any of the inactive ingredients in the product
- for more than 10 days for pain, unless directed by a doctor.
- for more than 3 days for a fever, unless directed by a doctor

Do not take this product
Do not give this product if you have

for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is acompanied by excessive phlegm (mucus), unless directed by a doctor.

- heart disease
- high blood pressure
- thyroid disease
- diabetes or difficulty in urination due to 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:

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

Overdose Warning:

Taking more than the recommended dose (overdose), may cause liver damage. In case of accidental overdose, contact a physician or Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

If you are pregnant or breast-feeding,

ask a health professional before use.

Directions: Do not take more than 4 doses in any 24 hours period.

Age	Dose
adults and children 12 years of age and over	2 tablets enery 4 hours.

children 6 to 12 years of age	1 tablet every 4 hours.
children under 12 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, mirocrystalline cellulose, povidone, silicon dioxide, sodium carboxymethyl starch, starch, stearic acid.

Questions or comments?

Please call (787) 767 3246

Domel Dometuss-G product label

NDC 53809-205-04

DOMETUSS-G

ACETAMINOPHEN/GUAIFENESIN

DEXTROMETHORPHAN HBR

PHENYLEPHRINE HCL

- Analgesic, Fever Reducer
- Expectorant
- Cough Suppressant
- Nasal Decongestant

Rev: 09/13

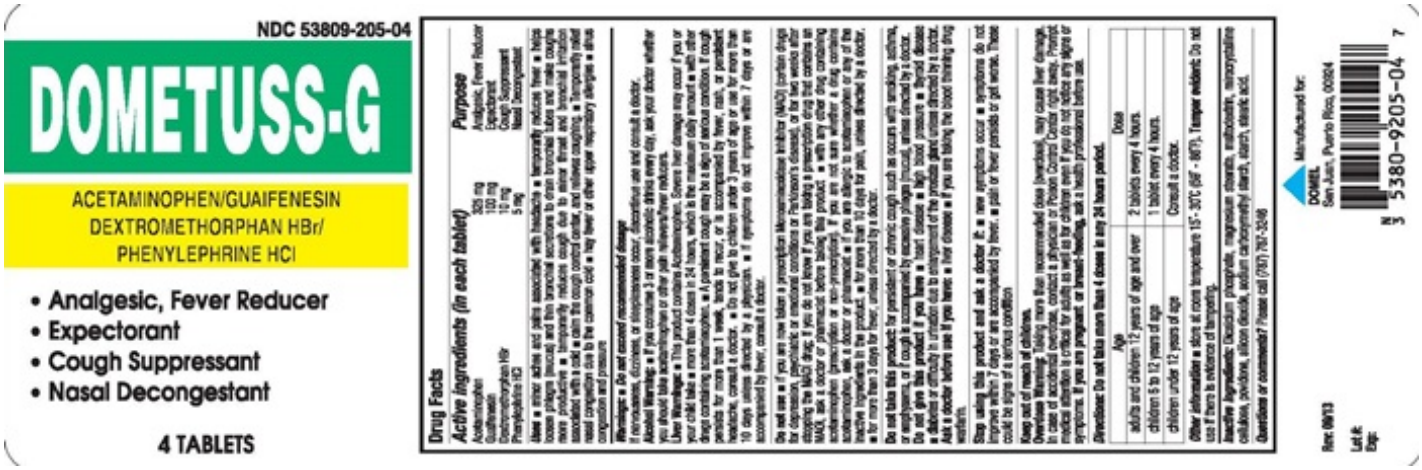
Lot #:

Exp:

Manufactured for:

DOMEL

San Juan, Puero Rico, 00924



DOMETUSS-G

acetaminophen, guaifenesin, dextromethrphan hbr, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53809-205
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, POTATO (UNII: 8I089SAH3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	DP

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53809-205-04	4 in 1 PACKAGE; Type 0: Not a Combination Product	01/21/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/21/2016	

Labeler - Domel Laboratories (808198837)

Registrant - Domel Laboratories (808198837)

Revised: 1/2016 Domel Laboratories