

DOMETUSS-DM- guaifenesin, dextromethorphan hbr liquid
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-DM

Drug Facts

Active ingredients (in each 5 mL tsp)

Guaifenesin 200mg

Dextromethorphan HBr 30 mg

Purpose

Expectorant

Cough suppressant

Keep out of reach of children.

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

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves coughs due to minor throat and bronchial irritation as may occur with a cold.

Warnings

- **Do not exceed recommended dosage.**
- A persistent cough may be a sign of a serious condition; if cough persists for more than one week, tend to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

Do not use 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
- 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 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.

If pregnant or breast-feeding

as a health professional before use.

Directions

Do not exceed more than 4 doses in any 24- hour period, or as directed by a physician.

Adults and children 12 years of age and over	Take 1 teaspoonful (5 mL) every 6 hours
Children 6 to under 12 years of age	Take 1/2 teaspoonful (2.5 mL) every 6 hours
Children under 6 years of age	Ask 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

Artificial grape flavor, citric acid, D&C red #33, FD&C blue #1, glycerin, methyl paraben (as preservative), propylene glycol, propyl paraben (as preservative), purified water, sodium citrate, sucralose.

Questions or comments?

Please call (787) 767-3246

DOMETUSS-DM product label

NDC 53809-201-01

DOMETUSS-DM

EXPECTORANT/COUGH SUPPRESSANT

Alcohol and Sugar

FREE

Grape Flavoe

1 Fl. Oz.

Rev: 10/13

Lot#:/EXP.DATE:

Manufactured for:

DOMEL

SAN JUAN, PUERTO RICO 00924

Drug Facts

Active ingredients (in each 5 mL tsp) **Purpose**
 Guaifenesin200 mg.....Expectorant
 Dextromethorphan HBr30 mg.....Cough suppressant

Uses • helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive • temporarily relieves coughs due to minor throat and bronchial irritation as may occur with a cold.

Warnings: • Do not exceed recommended dosage.
 • A persistent cough may be a sign of a serious condition; if cough persists for more than one week, tend to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.
 • Do not use 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 • if you are now taking a prescription Monoamineoxidase 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. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **If pregnant or breast-feeding, ask a health professional before use.**

NDC 53809-201-01

DOMETUSS-DM

EXPECTORANT / COUGH SUPPRESSANT



Alcohol and Sugar
FREE
 Grape Flavor
 1 Fl.Oz.

Drug Facts (continued)

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Rev: 10/13

Manufactured for:
 DOMEL
 SAN JUAN, PUERTO RICO 00924

LOT#:/EXP.DATE:

DOMETUSS-DM

guaifenesin, dextromethorphan hbr liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53809-201
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	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	grape	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53809-201-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2016	
2	NDC:53809-201-04	118 mL in 1 BOTTLE; 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)