

DOMETUSS-DM- guaifenesin, dextromethorphan hbr liquid
Domel Laboratories

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, tends 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	
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Dextromethorphan HBr30 mg.....	Cough suppressant
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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. 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.

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Rev: 10/13

Manufactured for:
DOMEL
SAN JUAN, PUERTO RICO 00924



LOT#:/EXP.DATE:

[Redacted]

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 Drug	M012	01/21/2016	

Labeler - Domel Laboratories (808198837)

Registrant - Domel Laboratories (808198837)