

**DOMETUSS-DMX- guaifenesin, dextromethorphan hbr, phenylephrine
hcl liquid**

Domel Laboratories

DOMETUSS-DMX

Drug Facts

Active ingredients (in each 5 mL teaspoonful) contains

Guaifenesin 200mg

Dextromethorphan HBr, USP 30 mg

Phenylephrine HCL, USP 10 mg

Purpose

Expectorant

Cough suppressant

Nasal decongestant

KEEP THIS AND ALL DRUGS OUT OF THE 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 drain bronchial tubes
- Temporarily relieves these symptoms occurring with a cold: nasal congestion, cough due to minor throat and bronchial irritation

Warnings - 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.

Ask a doctor before use if you have

- Heart Disease
- High Blood Pressure
- Thyroid Disease
- Diabetes
- Trouble urinating due to an enlarged prostate gland
- Cough that occurs with too much phlegm (mucus)
- Cough that lasts or is chronic such as bronchitis or emphysema

If pregnant or breast-feeding

as a health professional before use.

Stop use and ask a doctor if

- You get nervous, dizzy, or sleepless
- Symptoms do not get better within 7 days or are accompanied by a fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache.

These could be signs of a serious condition.

Directions

Do not exceed recommended dosage

Do not take more than 4 doses in any 24-hour period

age	dose
Adults and children 12 years of age and older	1 teaspoon every 6 hours
Children under 12 years of age	ask a doctor

Inactive ingredients

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

Other information

- Store at 15°-30° C (59°-86°F)

Questions or comments?

Please call (787) 767-3246

DOMETUSS-DMX product label

NDC 53809-203-01

DOMETUSS-DMX

COUGH SUPPRESSANT/EXPECTORANT/NASAL DECONGESTANT

Alcohol and Sugar

FREE

Grape Flavor

1 Fl. Oz. (30 mL)

Rev: 12/12

Tamper-Evident Disclosure: Do not use if there is evidence of tampering.

LOT#:/EXP.DATE:

Manufactured for:

DOMEL

SAN JUAN, PUERTO RICO 00924

Drug Facts

Active ingredients (in each 5 mL teaspoonful) contain: Purpose
Guaifenesin 200 mg Expectorant
Dextromethorphan HBr 30 mg Cough suppressant
Phenylephrine HCl 10 mg Nasal decongestant

Inactive ingredients: Citric Acid, D&C Red #33, FD&C Blue #1, Grape Flavor, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate, Sucralose.

Use: • Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.
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• Heart Disease • High Blood Pressure • Thyroid Disease
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Manufactured for:
DOMEL
SAN JUAN, PUERTO RICO 00924

53809 20301

DOMETUSS-DMX
NDC 53809-203-01
**COUGH SUPPRESSANT / EXPECTORANT
NASAL DECONGESTANT**

**Alcohol and Sugar
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Grape Flavor
1 fl. oz. (30 mL)**

Drug Facts (continued)

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Directions: • Do not exceed recommended dosage • Do not take more than 4 doses in any 24-hour period.

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Adults and children 12 years of age and over	1 teaspoon every 6 hours
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guaifenesin, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53809-203
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 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:53809-203-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2016	
2	NDC:53809-203-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2016	
3	NDC:53809-203-16	473 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)

Revised: 12/2024

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