DOMETUSS-DMX- guaifenesin, dextromethorphan hbr, phenylephrine hcl 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-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 occuring 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 persistant 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

DOMETUSS-DMX

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 final	part341	01/21/2016	

Labeler - Domel Laboratories (808198837)

Registrant - Domel Laboratories (808198837)

Revised: 12/2022 Domel Laboratories