DOMETUSS- chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride syrup
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

Drug Facts

Active ingredients (in each 5 ml-teaspoonful)	**Purpose**
Chlorpheniramine Maleate 4 mg	Antihistamine
Dextromethorphan HBr 20 mg	Cough suppressant
Phenylephrine HCl 10 mg	Nasal Decongestant

USE

- For temporary relief of runny nose, sneezing,itching of the nose or throat and itchy watery eyes due to hay fever.
- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold.
- Temporarily restores freer breathing through the nose

WARNINGS

DO NOT USE

- to sedate a child or to make a child sleepy
- 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
- thyroid disease
- trouble urinating due to enlarged prostate gland
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problems or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis or emphysema

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE

- taking sedatives or tranquilizers

- **When using this product**
  DO NOT EXCEED RECOMMENDED DOSAGE
- may cause marked drowsiness
- avoid alcoholic beverages
- Alcohol, sedatives, and tranquilizers may cause increased drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially with children.

STOP USE AND ASK A DOCTOR IF

you get nervous, dizzy, or sleepless.
- cough last more than 7 day, comes back, or is accompanied by fever, rash or persistent headaches. These could be signs of a serious condition.

IF PREGNANT OR BREAST FEEDING ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN. in case of accidental overdose, get medical help or contact a poison control Center right away.

Directions

Do not exceed more than 6 doses in any 24-hour period

Adults and children 12 years of age and over	Take 1 teaspoonful (5 mL) every 4 hours
Children 6 to under 12 years of age	Take 1/2 teaspoonful (2.5 mL) every 4 hours
Children under 6 years of age	Ask a doctor

Other Information

store at room temperature between 15°-30° C (59°-86°F)

Tamper-Evident Disclosure

Do not use this product if aluminum foil over bottle opening is torn, broken or missing.

Inactive ingredients

citric acid,grape flavor,glycerin hydroxyethylcellulose methylparaben,propylen glycol, propylparaben, purified water,sodiumcitrate,and sucralose.

Questions or comments?

Please call (787) 767-3246

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

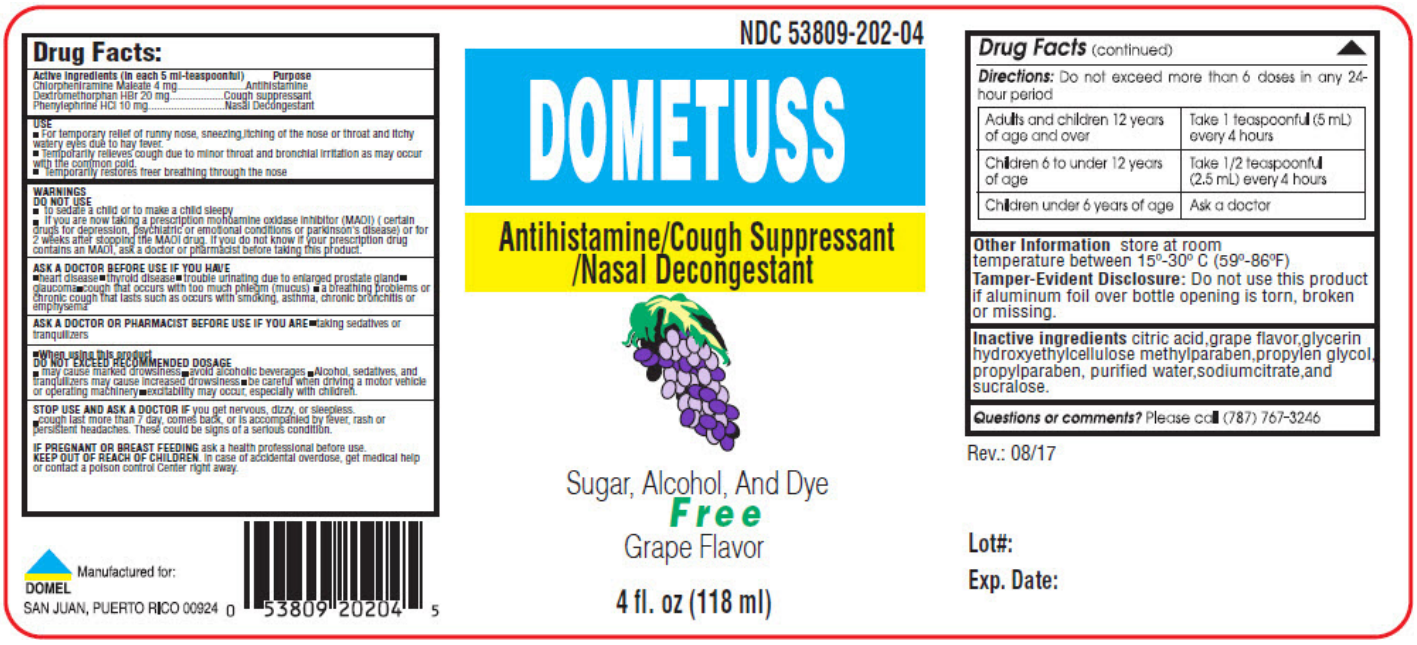
NDC 53809-202-04

DOMETUSS

Antihistamine/Cough Suppressant
/Nasal Decongestant

Sugar, Alcohol, And Dye
Free
Grape Flavor

4 fl. oz (118 ml)



DOMETUSS

chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53809-202
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	PHENYLEPHRINE	10 mg

UNII:1WS297W6MV)	HYDROCHLORIDE	in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)	
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:53809-202-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/01/2015	

Labeler - Domel Laboratories (808198837)

Revised: 12/2022 Domel Laboratories