# DOMETUSS- chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride liquid Domel Laboratories

-----

# **DOMETUSS**

**Drug Facts:** 

Active Ingredients (in each 5ml-teaspoonful)	Purpose
Chlorpheniramine Maleate 2mg	Antihistamine
Dextromethorphan HBr 10mg	Cough Suppresant
Phenylephrine HCl 5mg	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 days, comes back, or is accompanied by fever, rash or persitent 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	2 teaspoonful ( 10 ml )	
of age and over	every 4 hours.	
Children 6 to under 12 years	1 teaspoonful ( 5 ml ) every	
of age	4 hours.	
Children under 6 years of	Ask a doctor.	
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, flavor, methylparaben, propylparaben, propylene glycol, purified water, sodium citrate and sucralose.

## **Questions or comments?**

Please call (787) 767-3246.

# PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 53809-222-04

**DOMETUSS** 

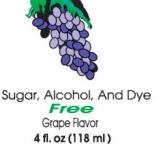
Antihistamine/Cough Suppressant/ Nasal Decongestant

Sugar, Alcohol, And Dye Free Grape Flavor

4 fl. oz (118 ml)







# Drug Facts (continued) Directions: Do not exceed more than 6 doses in any 24 hour period. Adults and children 12 years of age and over 2 years 1 teaspoonful (10 ml) every 4 hours. Children 6 to under 12 years of age Ask a doctor.

Other Information: store of room temperature between 15°-30°C (50°-86°F).

\*\*Tamper-Evident Disclosure: Do not use this product if aluminum foil over bottle opening is forn, broken or missing.

inactive ingredients: Citric acid, flavor, methylparaben, propylparaben, propylene glycol, purified water, sodium citrate and sucralose.

Questions or Comments? Please call (787) 767-3246.

REV-12-2023

Lot#: Exp.Date

# **DOMETUSS**

chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53809-222
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg in 118 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 118 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 118 mL	

# **Inactive Ingredients**

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLPARABEN (UNII: A218C7H19T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging			
# Item Code	Item Code Package Description		Marketing End Date
NDC:53809-222	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M012	03/06/2024	

# Labeler - Domel Laboratories (808198837)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Dextrum Laboratories		007392322	MANUFACTURE(53809-222)	

Revised: 8/2024 Domel Laboratories