

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 Suppressant
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 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	2 teaspoonful (10 ml) every 4 hours.
Children 6 to under 12 years of age	1 teaspoonful (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, 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)

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Nasal Decongestant



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REV-12-2023

Lot#:
Exp.Date



DOMEL Manufactured for:
SAN JUAN, PUERTO RICO 00924



0 53809 22204 3

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: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 118 mL
DEXTROMETHORPHAN HYDROBROMIDE (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: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53809-222-04	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	Business Operations
Dextrum Laboratories		007392322	MANUFACTURE(53809-222)