

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

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**DOMETUSS**

**Drug Facts:**

| <b>Active Ingredients (in each 5ml-teaspoonful)</b> | <b>Purpose</b>        |
|---|-----------------------|
| Chlorpheniramine Maleate 2mg                        | Antihistamine         |
| Dextromethorphan HBr 10mg                           | Cough<br>Suppresant   |
| Phenylephrine HCl 5mg                               | Nasal<br>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)

**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 free breathing through the nose.

**WARNINGS: DO NOT USE**

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**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 problem 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.

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)

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

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

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:53809-222 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength             | Strength      |
|--|-------------------------------|---------------|
| <b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)      | CHLORPHENIRAMINE MALEATE      | 2 mg in 5 mL  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 5 mL |
| <b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)      | PHENYLEPHRINE HYDROCHLORIDE   | 5 mg in 5 mL  |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)          |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)                    |          |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)                    |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                 |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                            |          |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR) |          |
| <b>SUCRALOSE</b> (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) |