

DOMETUSS-DA- chlorpheniramine maleate, phenylephrine hydrochloride 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-DA

Drug Facts

Active ingredients (in each 5 mL tsp)

Chlorpheniramine Maleate 1 mg

Phenylephrine HCL 2.5 mg

Purpose

Antihistamine

Nasal Decongestant

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Uses

- Temporarily relieves runny nose and sneezing
- itching of the nose or throat and itchy
- watery eyes due to hay fever or other respiratory allergies (allergic rhinitis)
- temporarily relieves nasal congestion due to common cold
- temporarily restores freer breathing through the nose

Warnings

- **Do not exceed recommended dosage.**
- A persistent cough may be a sign of a serious condition; if cough persists for more than one week, tend to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

Do not use this product

- for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor
- 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 two weeks after stopping the MAOI drug; if you do not know if you are taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product.

If pregnant or breast-feeding

as a health professional before use.

Directions

Do not exceed more than 4 doses in any 24- hour period, or as directed by a physician.

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

Other Information

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

Tamper Evident: Do not use if there is evidence of tampering.

Inactive ingredients

Artificial grape flavor, citric acid, D&C red #33, FD&C blue #1, glycerin, methyl paraben (as preservative), propylene glycol, propyl paraben (as preservative), purified water, sodium citrate, sucralose.

Questions or comments?

Please call (787) 767-3246

DOMETUSS-DA product label

NDC 53809-206-04

DOMETUSS-DA

NASAL DECONGESTANT & ANTIHISTAMINIC

- Itchy, Watery Eyes

- Runny Nose
- Stuffy Nose
- Sneezing

bubble gum flavor

4 fl. oz. (118 mL)

Rev: 05/13

Lot #

Exp:

Manufactured for:

DOMEL

SAN JUAN, PUERTO RICO 00924

Drug Facts

Active ingredients (by each 5 mL, 16.9 fl. oz.):
 Chlorpheniramine Maleate... 1 mg
 Phenylephrine HCl... 2.5 mg

Warnings: • Do not exceed recommended dosage. • May cause excitability in children. • If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor. • May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. • Avoid alcoholic beverages while taking this product. • Do not take this product if you or your child are taking sedatives or tranquilizers, without first consulting your doctor. • Use caution when driving a motor vehicle or operating machinery.

Do not use this product: • If you or your child has heart disease, high blood pressure, thyroid disease, diabetes, unless directed by a doctor. • If you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma, unless directed by a doctor. • If you or your child are now taking a prescription Monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions or Parkinson's disease), or for two weeks after stopping the MAOI drug. If you do not know if you or your child are taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product. • If you have difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

NDC 53809-206-04

DOMETUSS-DA

NASAL DECONGESTANT & ANTIHISTAMINIC

- Itchy, Watery Eyes
- Runny Nose
- Stuffy Nose
- Sneezing



Bubble Gum Flavor
4 fl.oz. (118 mL)

Drug Facts (continued)

Stop using and ask a doctor: • If symptoms do not improve within 7 days or are accompanied by fever.

• If pregnant or breast-feeding, ask a health professional before use. • Keep out of reach of children. In case of 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.

children 6 to under 12 years of age	take 2 (teaspoonfuls (10 mL)) every 4 hours
children 4 to under 6 years of age	do not use unless directed by a doctor
children under 4 years of age	do not use

Other Information: • store at room temperature 15° - 30°C (59° - 86°F). • Tamper evident: Do not use if there is evidence of tampering.

Inactive ingredients: artificial bubble gum flavor, citric acid, D & C red #33, methylparaben (as preservative), natriol, propylene glycol, propylparaben (as preservative), purified water, sodium citrate, sucralose.

Questions or comments? Please call (787) 767-3248

Rev: 05/13
Lot #:
Exp:

DOMETUSS-DA

chlorpheniramine maleate, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53809-206
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9J9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
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CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
HYDROXYETHYL CELLULOSE (2000 MPAS 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	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53809-206-04	118 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)