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

Phenylphrine 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 persistant 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 persistant headache, consult a doctor.

Do not use this product

- for persistant 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 Monoaminooxidase 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 preserative), propylene glycol, propyl paraben (as preseratie, 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, Waterl Eyes
- Runny Nose
- Stuffy Nose
- Sneezing

bubble gum flavor

4 fl. oz. (118 mL)

Rev: 05/13

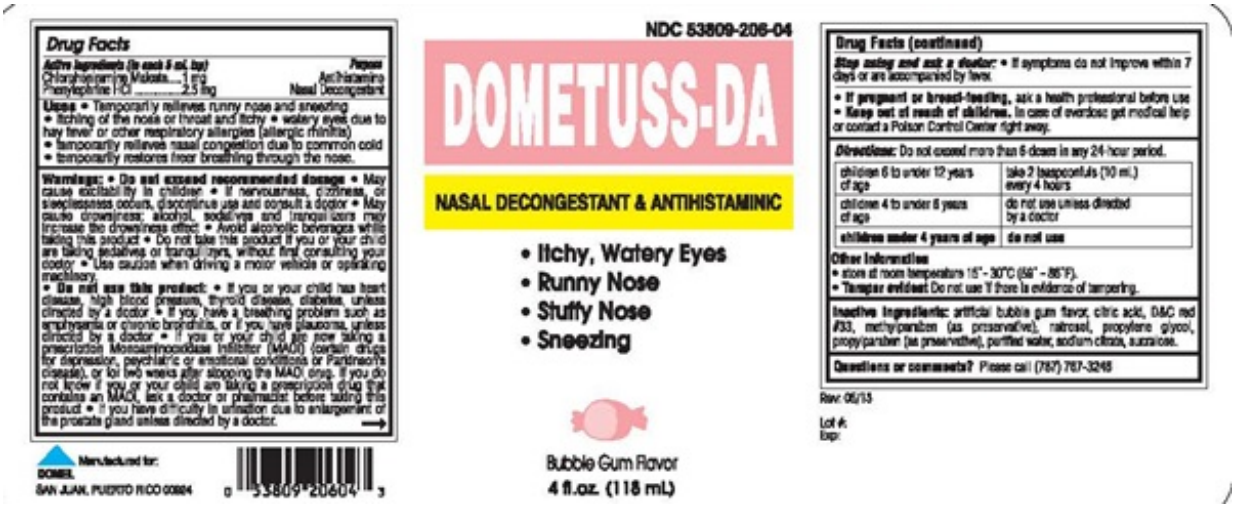
Lot #

Exp:

Manufactured for:

DOMEL

SAN JUAN, PUERTO RICO 00924



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: V1Q0O9OJ9Z) (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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
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	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)

Revised: 11/2019 Domel Laboratories