

DOMETUSS-NR- dextromethorphan hydrobromide, chlorpheniramine maleate, and phenylephrine hydrochloride tablet

Domel Laboratories

DOMETUSS-NR

Drug Facts

Active ingredients (in each tablet)		Purpose
Dextromethorphan HBr	20 mg	Cough Suppressant
Chlorpheniramine Maleate	4 mg	Antihistamine
Phenylephrine HCl	10 mg	Nasal decongestant

Uses

- Temporarily relieves
 - runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever.
 - Nasal congestion due to the common cold.
 - coughs due to minor throat and bronchial irritation as may occur with a cold.

Warnings

- ***Do not exceed recommended dosage***

Do not use

- if you are now taken a prescription Monoaminoxidase 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.

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.

Stop using this product and ask a doctor if

- you get nervous, dizzy or sleepless
- cough lasts more than 7 days, comes back or is accompanied by fever, rash or persistent headaches, these could be signs of a serious condition.

When using this product

- Excitability may occur, especially in children
- May cause drowsiness
- alcohol, sedatives and tranquilizers may increase the drowsiness effect
- Avoid alcoholic beverages while taking this product
- Use caution when driving motor vehicle or operating machinery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults even if you do not notice signs or symptoms.

If you are pregnant or breast-feeding, ask a health professional before use.

Directions

Do not take more than 6 tablets in 24 hours, or as directed by a doctor.

Age	Dose
adults and children 12 years of age and over	1 tablet every 4 hours.
children under 12 years of age	Consult a doctor before 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

Carbomer, Dicalcium Phosphate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide, Talc.

Questions or comments?

Please call (787) 767-3246

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

NDC 53809-240-01

DOMETUSS-NR

DEXTROMETHORPHAN HBr/ CHLORPHENIRAMINE
MALEATE/ PHENILEPHRINE HCl

- Cough Suppressant
- Antihistamine
- Nasal decongestant

100 TABLETS

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MALEATE/ PHENILEPHRINE HCl

- Cough Suppressant
- Antihistamine
- Nasal decongestant

Manufactured for:
DOMEL PHARMA
SAN JUAN, PUERTO RICO 00924



100 TABLETS

Drug Facts (continued)	
Stop using this product and ask a doctor if: • you get nervous, dizzy or sleepless • cough lasts more than 7 days, comes back or is accompanied by fever, rash or persistent headaches, these could be signs of a serious condition.	
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Questions or comments? Please call (787) 767-3246	
Manufactured for: Domel Laboratories, Inc. San Juan, Puerto Rico. 00924	

Rev: 11/18

Lot #:
Exp:

DOMETUSS-NR

dextromethorphan hydrobromide, chlorpheniramine maleate, and phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53809-240
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	13mm
Flavor		Imprint Code	KL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53809-240-01	100 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 drug	M012	01/21/2016	

Labeler - Domel Laboratories (808198837)

Establishment

Name	Address	ID/FEI	Business Operations
Lex Inc		046172888	MANUFACTURE(53809-240)

Revised: 12/2024

Domel Laboratories