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

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

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 final	part341	01/21/2016	

Labeler - Domel Laboratories (808198837)

Establishment

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

Revised: 12/2021 Domel Laboratories