NEOTUSS S/F GRAPE-MENTHOL FLAVOR- guaifenesin, dextromethorphan hbr liquid

DORAL PHARMAMEDICS INC dba A.G. Marin Pharmaceuticals

NeoTuss S/F Grape-Menthol Flavor

Guaifenesin 200 mg / 5 mL - Purpose: Expectorant

Dextromethorphan HBr 30 mg / 5 mL - Purpose: Antitussive

Artificial and natural flavors, glycerin, hydroxyethylcellulose, menthol, methylparaben, propylene glycol, propylparaben, purified water, sorbitol, and sucralose.

Temporarily relieves cough due to minor bronchial irritations as may occur with the common cold. Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Adults and children over 12 years of age: Oral dose in one teaspoonful (5 mL) every 6-8 hours, or as directed by a physician.

Children 6 to under 12 years of age: 1/2 teaspoonful (2.5 mL) every 6-8 hours, or as directed by a physician.

Children under 6 years of age: Only as directed by a physician.

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Expectorant and Antitussive (cough suppressant)

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In case of accidental overdose, seek the advice of a health professional or contact a Poison Control Center immediately.

A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a physician.

Do not take this product for persistent cough or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a physician.

Do not use 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 are uncertain whether your prescription drug contains a MAOI, consult a health professional before taking this product.

If pregnant or breast-feeding, ask a health professional before using this product.

Shake well before use.

Do not use this product if the seal is torn, broken or missing.

Pharmacist: Preserve and dispense in tight, light-resistant containers as defined in the USP.

Store between 15°-30°C (59°-86°F).



Package Label - Principal Display Panel

16 FL. OZ (474 mL) NDC: 12539-555-16

NEOTUSS S/F GRAPE-MENTHOL FLAVOR

guaifenesin, dextromethorphan hbr liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12539-555
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
METHYLPARABEN (UNII: A2I8C7HI9T)	7.55 mg in 5 mL		
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.85 mg in 5 mL		
SUCRALOSE (UNII: 96K6UQ3Z D4)	3.35 mg in 5 mL		
SORBITOL (UNII: 506T60A25R)	1250 mg in 5 mL		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	750 mg in 5 mL		
GLYCERIN (UNII: PDC6A3C0OX)	1750 mg in 5 mL		
HYDROXYETHYLCELLULOSE (UNII: T4V6TWG28D)	2.1 mg in 5 mL		
MENTHOL (UNII: L7T10EIP3A)	0.4 mg in 5 mL		
WATER (UNII: 059QF0KO0R)	1023 mg in 5 mL		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:12539-55	5- 474 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2025	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	03/06/2025		

Labeler - DORAL PHARMAMEDICS INC dba A.G. Marin Pharmaceuticals (076007996)

Establishment				
Name	Address	ID/FEI	Business Operations	
DEXTRUM LABORATORIES INC		007392322	manufacture(12539-555)	

Revised: 3/2025 DORAL PHARMAMEDICS INC dba A.G. Marin Pharmaceuticals