

**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.

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.

Expectorant and Antitussive (cough suppressant)

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.

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

1 FL. OZ (30 mL) NDC: 12539-555-01

WARNING: A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, leads to nasal, 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.

Use with care: 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 an MAOI, consult a health professional before taking this product. If a pregnant or breast-feeding, ask a health professional before use.

SHAKE WELL BEFORE USE. DO NOT USE THIS PRODUCT IF SEAL IS TORN, BROKEN OR MISSING. KEEP OUT OF REACH OF CHILDREN.

In case of accidental overdose, seek the advice of a health professional or contact a Poison Control center immediately. Questions or Comments: Please call 305-898-5333 Monday through Friday from 8:30AM to 4:30PM (Eastern Time) Rev 07/19

NDC 12539-555-01

**EXPECTORANT ANTITUSSIVE
COUGH FORMULA**

Neotuss S/F

Grape-Menthol Flavor

• PHYSICIAN SAMPLE •

**SUGAR, ALCOHOL, DYE,
CODEINE, ANTIHISTAMINE
FREE**

CONTENTS: 1 FL. OZ. (30 ml)

Manufactured for:
A.G. Marin Pharmaceuticals
Miami, FL 33144

Active Ingredients: (in each 5 mL)	Purpose
Guafenesin 200 mg	Expectorant
Dextromethorphan HBr 30 mg	Antitussive

Uses: 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.

Directions: Adults and children over 12 years of age: Oral dose is one teaspoonful (5 mL) every 6-8 hours, or as directed by a physician. Children 11 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.

Other Information: Pharmacist: Preserve and dispense in tight, light-resistant container as defined in the USP. Store between 15°-30°C (59°-86°F).

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

Lot #/Exp. Date: unvarnished area

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: 96K6UQ3ZD4)	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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12539-555-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/28/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/28/2025	

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: 2/2025

DORAL PHARMAMEDICS INC dba A.G. Marin Pharmaceuticals