NEOTUSS PLUS- dextromethorphan hbr, chlorpheniramine maleate, phenylephrine hcl liquid DORAL PHARMAMEDICS INC dba A.G. Marin Pharmaceuticals

NeoTuss Plus Cherry Flavor 16 Oz

Dextromethorphan HBr 30 mg / 5 mL

Chlorpheniramine Maleate 4 mg / 5 mL

Phenylephrine HCl 7.5 mg / 5 mL

Artificial and natural flavors, citric acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium carboxymethylcellulose, sorbitol, and sucralose.

Antitussive, Antihistamine, and Decongestant.

Temporarily relieves cough due to minor throat and bronchial irritations associated with the common cold or inhaled irritants. Helps thin bronchial passageways of bothersome mucus.

Temporarily relieves nasal congestion due to the common cold, sinusitis, hay fever or other respiratory allergies.

Temporarily relieves sneezing, itching of the nose or throat, and itchy watery eyes due to hay fever or other respiratory allergies.

Adults and children over 12 years of age: One teaspoonful (5 mL) every 6-8 hours; do not exceed 4 teaspoonfuls in 24 hours period.

Children 6-12 years of age: 1/2 teaspoonful (2.5 mL) every 6-8 hours; do not exceed 2 teaspoonfuls in 24 hours period. Children under 6 years of age: Ask a doctor.

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

Shake well before use.

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Temporarily relieves nasal congestion due to the common cold, sinusitis, hay fever or other respiratory allergies.

Temporarily relieves sneezing, itching of the nose or throat, and itchy watery eyes due to hay fever or other respiratory allergies.

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

Do not take this product if you have a persistent or chronic cough, such as occurs with smoking, asthma, emphysema or when cough is accompanied by excessive secretions except under the advice and supervision of a physician.

Do not take other sedatives, tranquilizers or alcohol while taking this medication.

Do not use if you are taking monoamine oxidase inhibitors or other sympathomimetics.

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

Sympathomimetic amines should be used with caution in patients with hypertension, diabetes mellitus, heart disease, peripheral vascular disease, increased intraocular pressure, hyperthyroidism or prostatic hypertrophy. May cause drowsiness. Sedatives and tranquilizers may increase the drowsiness effect.

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

Store between 15°-30°C (59°-86°F).

Do not accept this product if the safety seal is broken or missing.

Keep a box for information.

Sympathomimetic amines should be used with caution in patients with hypertension, diabetes mellitus, heart disease, peripheral vascular disease, increased intraocular pressure, hyperthyroidism or prostatic hypertrophy. May cause drowsiness. Sedatives and tranquilizers may increase the drowsiness effect.

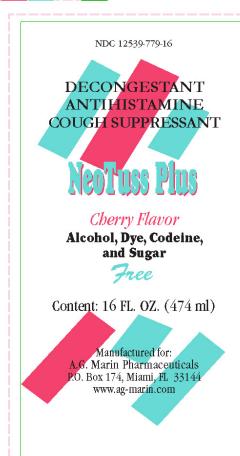
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Temporarily relieves nasal congestion due to the common cold, sinusitis, hay fever or other respiratory allergies.

Temporarily relieves sneezing, itching of the nose or throat, and itchy watery eyes due to hay fever or other respiratory allergies.



Drug Facts

Active Ingredients: In one tsp. (5ml) Purpose
Dextromethophan HBr 30 mg
Chlomheniramine Maleate Amg
Phenylephrine HCl 7.5 mg
Pocongestant

Uses: Temporarily relieves cough due to minor throat and bronchial irritations associated with the common cold or inhaled irritants. Helps thin bronchial passageways of bothersome mucus. Temporarily relieves nasal congestion due to the common cold, sinusitis, hay fever or other respiratory allergies. Temporarily relieves sneezing, itching of the nose or throat, and itchy watery eyes due to hay fever or other respiratory allergies.

WARNING: Sympathomimetic amines should be used with caution in patients with hypertension, diabetes mellitus, heart disease, peripheral vascular disease, increased intraocular pressure, hyperthyroidism or prostatic hypertrophy May cause

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Do not take this product if you have a persistent or chronic cough, such as occurs with smoking, asthma, emphysema or when cough is accompanied by excessive secretions except under the advice and supervision of a physician.

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Do not take other sedatives, tranquilizers or alcohol while taking this medication.

Do not use if you are taking monoamine oxidase inhibitors or other sympathomimetics.

If you are 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.

Drug Facts (continued)

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

Directions: Adults and children over 12 years of age: One teaspoonful (5 mL) every 6-8 hours; do not exceed 4 teaspoonfuls in 24 hours period. Children 6-12 years of age: 1/2 teaspoonful (2.5 mL) every 6-8 hours; do not exceed 2 teaspoonfuls in 24 hours period. Children under 6 years of age: Ask a doctor.

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

Inactive Ingredients: Artificial and natural flavors, citric acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium carboxymethylcellulose, sorbitol, and sucralose.

Questions?: Please call 305-593-5333, Monday — Friday from 8:30 AM to 4:30 PM (Bastern Time).



Lot #/Exp. Date: Rev. 04/2020

BAY TECH/LABEL

Package Label - Principal Display Panel

16 FL. OZ (474 mL) NDC: 12539-779-16

LT07865 (0077).ai (04/09/2020, 12:54 pm) DORAL PHARMAMEDICS, INC. • 136309

NeoTuss Plus 16oz NDC 12539-779-16

NEOTUSS PLUS

dextromethorphan hbr, chlorpheniramine maleate, phenylephrine hcl liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:12539-779 Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	4 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	7.5 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	300 mg in 5 mL	
SORBITOL (UNII: 506T60A25R)	1750 mg in 5 mL	
GLYCERIN (UNII: PDC6A3C0OX)	500 mg in 5 mL	
CITRIC ACID (UNII: 2968PHW8QP)	10 mg in 5 mL	
METHYLPARABEN (UNII: A2I8C7HI9T)	9 mg in 5 mL	
PROPYLPARABEN (UNII: Z8IX2SC10H)	1 mg in 5 mL	
SODIUM CARBOXYMETHYL STARCH (UNII: H8AV0SQX4D)	30 mg in 5 mL	
SUCRALOSE (UNII: 96K6UQ3ZD4)	7.5 mg in 5 mL	
WATER (UNII: 059QF0KO0R)	2331 mg in 5 mL	

ı	P	Packaging Packag			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:12539-779- 16	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(12539-779)		

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