NEOGEN-D- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution
Kramer Novis

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.

NEOGEN® -D

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dextromethorphan HBr, 30 mg

Guaifenesin, 200 mg

Phenylephrine HCL, 7.5 mg

Purposes

Antitussive

Expectorant

Nasal Decongestant

Uses

• helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.

• temporarily relieves these symptoms occurring with the common cold, sinusitis, hay fever or other respiratory allergies.

- nasal congestion
- cough due to minor throat and bronchial irritation

Warnings

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 do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

• Heart disease • High blood pressure • Thyroid disease • Diabetes • Trouble urinating due to enlarged prostate gland • cough that occurs with too much phlegm (mucus) • a cough that lasts such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Ask a doctor or pharmacist before use if you are taking any other oral nasal decongestant or stimulant.

When using this product do not use more than directed.

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless • symptoms do not get better within 7 days or are accompanied by fever • cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

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

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not take more than 4 doses in any 24-hour period. Shake well before using.

Every 6-8 hours	**Adults and children 12 years of age and over**	Take one teaspoonful (5 mL)
	Children 6 to under 12 years of age	Take 1/2 teaspoonful (2.5 mL)
	Children under 6 years of age	Consult a doctor

Other Information

• Store at controlled room temperature 15°C-30°C (59°F-86°F). Avoid excessive heat or humidity.

• Tamper Evident Feature: Do not use if inner seal is torn, broken or missing.

Inactive Ingredients

Potassium sorbate, sodium benzoate, citric acid, propylene glycol, sodium citrate, sucrose, sorbitol, vegetable glycerin, sucralose, raspberry flavor and purified water

Contains the same active ingredients as Neo Tuss®-D*

DEXTROMETHORPHAN HBr
Antitussive

GUAIFENESIN
Expectorant

PHENYLEPHRINE HCL
Nasal Decongestant

• Alcohol Free • Dye Free

• Codeine Free • Sugar Free

Raspberry Flavor

Manufactured in the USA for Kramer Novis, San Juan, PR 00917.

T:(787) 767-2072 www.kramernovis.com

* Neo Tuss®-D* is a registered trademark of A.G. Marin Pharmaceuticals. This product is not manufactured, distributed or marketed by A.G. Marin Pharmaceuticals.

Packaging

Drug Facts

Active Ingredients *(in each 5 mL tsp)* — **Purposes**

Dextromethorphan HBr, 30 mg — Antitussive

Guaifenesin, 200 mg — Expectorant

Phenylephrine HCl, 7.5 mg — Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with the common cold, sinusitis, hay fever or other respiratory allergies:
  - nasal congestion
  - cough due to minor throat and bronchial irritation

Warnings

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Ask a doctor before use if you have • Heart disease • High blood pressure • Thyroid disease • Diabetes • Trouble urinating due to enlarged prostate gland • cough that occurs with too much phlegm (mucus) • a cough that lasts such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Ask a doctor or pharmacist before use if you are taking any other oral nasal decongestant or stimulant

When using this product do not use more than directed. ▶

NDC 52083-699-16

NEOGEN® -D

Contains the same active ingredients as NeoTuss®-D*

DEXTROMETHORPHAN HBr
Antitussive

GUAIFENESIN
Expectorant

PHENYLEPHRINE HCl
Nasal Decongestant

•Alcohol Free •Dye Free
•Codeine Free •Sugar Free

Raspberry Flavor

Net Content: 16 fl oz (473 mL)

Manufactured in the USA for
Kramer Novis, San Juan, PR 00917
T: (787) 767-2072 www.kramernovis.com

KramerNovis
Pharmaceuticals within reach of patients

Drug Facts (continued)

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless • symptoms do not get better within 7 days or are accompanied by fever • cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children**. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

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Inactive Ingredients

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Rev. 08/18

NEOGEN-D

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-699
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	7.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-699-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/10/2018	

Labeler - Kramer Novis (090158395)

Revised: 11/2018 Kramer Novis