

G-TRON PED- 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.

Drug Facts

Active Ingredients (in each 5 mL tsp)	Purpose
Dextromethorphan HBr, 15 mg.....	Cough Suppressant
Guaifenesin, 350 mg.....	Expectorant
Phenylephrine HCl, 10 mg.....	Nasal decongestant

Uses

- suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive
- temporarily relieves nasal congestion due to a cold

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

- diabetes
- heart disease
- thyroid disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.

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 last more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be a 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 6 doses in any 24-hour period

EVERY 4 HOURS

- Adults and Children 12 years of age and older: 5 mL (1 tsp)
- Children 6 to under 12 years of age: (2.5 mL (1/2 tsp)
- Children under 6 years of age: Consult physician

Other information

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

Store at controlled room temperature 15-30°C (59-86°F).

Avoid excessive heat and humidity.

Inactive ingredients Citric acid, flavor, hydroxyethyl cellulose, methyl paraben, potassium citrate, polyethylene glycol, propyl paraben, purified water, sorbitol and sucralose.

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

Tel: (787) 767-2072 / www.kramernovis.com

Principal Display Panel

G-TRON® PED

COUGH SUPPRESSANT

EXPECTORANT

NASAL DECONGESTANT

Contains the same active ingredients as Broncotron® PED

SUGAR FREE

DYE FREE

ALCOHOL FREE

GRAPE FLAVOR

16 Fl. Oz. (474 mL)

KRAMER-NOVIS

NDC 52083-678-16

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EXPECTORANT
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Contains the same active ingredients as
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SUGAR FREE

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GRAPE FLAVOR

16 Fl.oz. (474 mL)



Drug Facts (continued)

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 6 doses in any 24-hour period

EVERY 4 HOURS	Adults and Children 12 years of age and over	5 mL (1 tsp)
	Children 6 to under 12 years of age	2.5 mL (1/2 tsp)
	Children under 6 years of age	Consult physician

Other information

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*** Broncotron[®] PED is a registered trademark of Seyer Pharmatec. This product is not manufactured, distributed or marketed by Seyer Pharmatec.**



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Lot #
Exp. Date

G-TRON PED

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-678
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	350 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYDROXYETHYL CELLULOSE (280 MPA.S AT 5%) (UNII: B24JYI97VR)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

SUCRALOSE (UNII: 96K6UQ3ZD4)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-678-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/27/2014	

Labeler - Kramer Novis (090158395)

Revised: 9/2019

Kramer Novis