

G-TUSICOF- dextromethorphan, guaifenesin, and phenylephrine syrup

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.

G-TUSICOF

COUGH SUPPRESSANT - EXPECTORANT NASAL DECONGESTANT

Drug Facts

Active ingredients (in each 5mL tsp)	Purpose
Dextromethorphan Hydrobromide, 20 mg	Cough suppressant
Guaifenesin, 400 mg	Expectorant
Phenylephrine HCl, 10 mg	Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
 - 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

- 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 lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious illness.

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 and older: 5 mL (1 tsp)
- Children under 12 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 or humidity

Inactive ingredients

Artificial and natural flavors, citric acid, glycerin, menthol, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate and sucralose

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

PRINCIPAL DISPLAY PANEL - G-TUSICOF

Drug Facts

Active Ingredients (in each 5 mL tsp) **Purpose**
 Dextromethorphan Hydrobromide, 20 mg.....Cough Suppressant
 Guaifenesin, 400 mg.....Expectorant
 Phenylephrine HCl, 10 mg.....Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
 - 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

- 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

Lot #

Exp. Date

NDC 52083-639-16

G-TUSICOF®**Compare to Tusicof®****COUGH SUPPRESSANT - EXPECTORANT
NASAL DECONGESTANT****SUGAR & ALCOHOL FREE**

NO SACCHARIN - NO SORBITOL - NO ASPARTAME - NO DYE - NO PPA

16 Fl.oz. (474 mL)

**Drug Facts (continued)****Stop use and ask a doctor if**

- 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 6 doses in any 24-hour period

**EVERY
4 HOURS**

Adults and Children 12 years of age and over 5 mL (1 tsp)

Children under 12 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 or humidity.

Inactive Ingredients

Artificial and natural flavors, citric acid, glycerin, menthol, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate and sucralose.

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



NDC 52083-639-16

G-TUSICOF**COUGH SUPPRESSANT - EXPECTORANT
NASAL DECONGESTANT****SUGAR & ALCOHOL FREE**

NO SACCHARIN - NO SORBITOL - NO ASPARTAME - NO DYE - NO PPA

16 Fl. oz. (474 mL)

Kramer Novis

Pharmaceuticals within reach of patients

G-TUSICOF

dextromethorphan, guaifenesin, and phenylephrine syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-639
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 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)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (Mint Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-639-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/24/2012	

Labeler - Kramer Novis (090158395)

Registrant - Kramer Novis (090158395)

Revised: 11/2019

Kramer Novis