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.

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 occuring 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

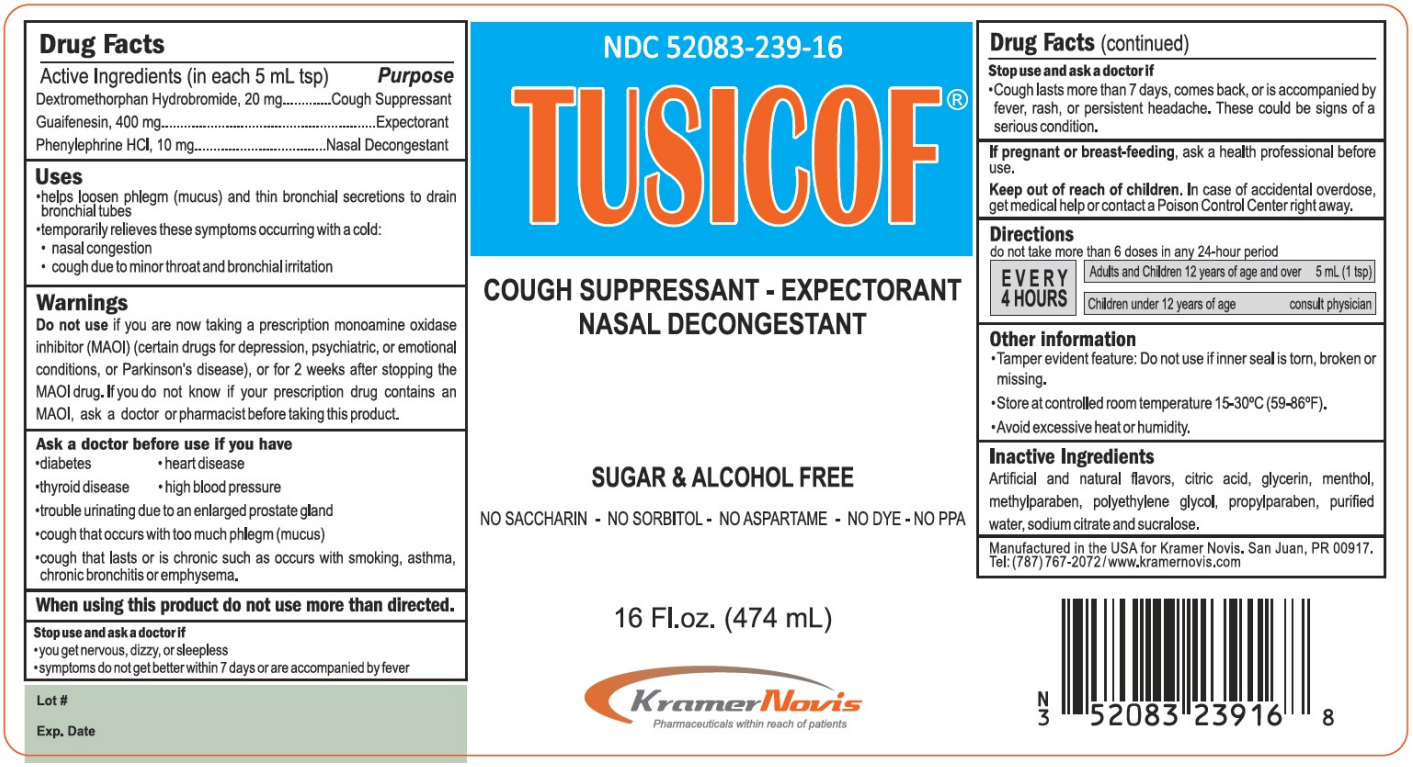
- Tamper evident feature: Do not use if inner seal is torn, broken or missing
- Store at controlled room temperature 15-30°C (59-86°F)
- Avoid excessive heat or humidity

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 - TUSICOF



NDC 52083-239-16

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

TUSICOF

dextromethorphan, guaifenesin, and phenylephrine syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-239
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:52083-239-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2010	
2	NDC:52083-239-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2010	
3	NDC:52083-239-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/17/2010	

Labeler - Kramer Novis (090158395)

Registrant - Kramer Novis (090158395)

Revised: 11/2019 Kramer Novis