TUSSLIN- dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride 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.

TUSSLIN®

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dextromethorphan HBr, 28 mg

Guaifenesin, 388 mg

Phenylephrine HCl, 10 mg

Purposes

Antitussive

Expectorant

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 cough 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
• heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to the enlarged prostate gland • cough that occurs with too much phlegm (mucus) • a cough that lasts or is chronic 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

• Take every 6 hours, or as directed by a doctor.

Adults and children 12 years of age and older	Take one teaspoonful (5 mL). Do not exceed 4 teaspoonfuls in 24 hours
Children 6 to under 12 years of age	Take 1/2 teaspoonful (2.5 mL). Do not exceed 2 teaspoonfuls in 24 hours
Children 2 to under 6 years of age	Take 1/4 teaspoonful (1.25 mL). Do not exceed 1 teaspoonful in 24 hours
Children under 2 years of age	Consult a doctor

Other information

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

Inactive ingredients

Citric acid, flavor, glycerin, methylparaben, propylparaben, polyethylene glycol, purified water, sodium citrate, and sucralose.

Questions or comments?

Call weekdays from 8 AM to 4 PM AST at **1-787-767-2072**. San Juan, PR 00917
www.kramernovis.com

NDC 52083-622-16

Contains the same active ingredients as Giltuss®*

Sugar, Alcohol, and Dye **FREE**

GRAPE FLAVOR

Manufactured in the USA for

Kramer Novis

*Giltuss® is a registered trademark of Gil Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Gil Pharmaceutical Corp.

Packaging

TUSSLIN

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-622
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	28 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	388 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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	PURPLE (clear, purple)	**Score**	
Shape		**Size**	
Flavor	GRAPE (artificial grape flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-622-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2014	

Labeler - Kramer Novis (090158395)

Revised: 9/2019 Kramer Novis