

**TUSSLIN PEDIATRIC- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops
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 1 mL)	Purpose
Dextromethorphan HBr, 7.5 mg.....	Antitussive
Guaifenesin, 88 mg.....	Expectorant
Phenylephrine HCl, 2.5 mg.....	Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily relieves:
- nasal congestion due to the common cold
- cough due to minor throat and bronchial irritation as may occur with the common cold

Warnings

Do not use

in child who is 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 child's prescription drug contains a MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if your child has

- heart disease
- thyroid disease
- high blood pressure
- diabetes
- a cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with asthma

When using this product do not exceed recommended dosage

Stop use and ask a doctor if

- new symptoms occur
- your child gets 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 use more than 4 doses in any 24-hour period

Children 6 to under 12 years of age

- 2 mL every 6 hours, do not exceed 4 doses.

Children 2 to under 6 years of age

- 1 mL every 6 hours, do not exceed 4 doses, or as directed by a doctor.

Children under 2, consult a doctor

- measure with the dosage device provided. Do not use any other device.

Other information

Tamper Evident Feature: Do not use if cap 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, flavors, menthol, methyl paraben, monoammonium glycyrrhizinate, polyethylene glycol, propylene glycol, propyl paraben, purified water, sorbitol and sucralose.

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

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www.kramernovis.com

Principal Display Panel

TUSSLIN®

PEDIATRIC DROPS

Contains the same active ingredients as Glituss® Pediatric

Antitussive

Expectorant

Nasal Decongestant

Sugar, Alcohol & Dye Free

NET CONTENT: 30 mL (1 Fl. Oz.)

KRAMER-NOVIS



TUSSLIN PEDIATRIC

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-623
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 1 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	88 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-623-01	30 mL in 1 BOTTLE, DROPPER; 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

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