

**TUSSI PRES PEDIATRIC- guaifenesin, phenylephrine hcl,dextromethorphan hydrobromide 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.*

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**TUSSI PRES PEDIATRIC**

*Drug Facts*

**Active Ingredients (In each 5 mL teaspoon)**

Dextromethorphan HBr 5 mg

Guaifenesin 75 mg

Phenylephrine HCl 2.5 mg

**Purpose**

Antitussive (Anti-Cough)

Expectorant

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 and cough due to minor throat and bronchial irritation.

**Warnings:**

**Do not use:** • in a child under 2 years of age. • in a 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 an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if your child has:**

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

**Do not use more than the recommended dose.**

**Stop use and ask a doctor if:** • your child gets 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 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.

Adults & Children 12 years of age and older	Take 4 teaspoons (20 mL) every 4 hours, as needed.
Children 6 to under 12 years of age	Take 2 teaspoons (10 mL) every 4 hours, as needed.
Children 2 to under 6	Take one pre-measured single dose package (1 teaspoon or 5 mL) every 4 hours, as needed.
Children under 2 years	Do not use.

***Other Information:***

- Tamper Evident. Do not use if packet is torn, cut or opened.
- Store at controlled room temperature 15° to 30°C (59° to 86°F).
- Avoid excessive heat or humidity.

***Inactive Ingredients:***

Citric acid, Flavor, Glycerin, Methylparaben, Propylene glycol, Propylparaben, Purified water, Sodium citrate and Sucralose

**COUGH SUPPRESSANT, EXPECTORANT, NASAL DECONGESTANT**

**SUGAR, ALCOHOL, SACCHARIN, SORBITOL & DYE FREE**

**ORANGE FLAVOR**

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

1 (787) 767-2072 [www.kramernovis.com](http://www.kramernovis.com)

**Packaging**

TEAR AND SQUEEZE

NDC 52083-232-05

# TUSSI-PRES

**Pediatric**  
COUGH SUPPRESSANT, EXPECTORANT  
NASAL DECONGESTANT  
SUGAR, ALCOHOL, SACCHARIN, SORBITOL & DYE FREE  
ORANGE FLAVOR

**Drug Facts**

**Active Ingredients** (In each 5 mL teaspoon) **Purpose**  
Dextromethorphan HBr 5 mg, Antitussive (Anti-Cough)  
Guaifenesin 75 mg, Expectorant  
Phenylephrine HCl 2.5 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 and cough due to minor throat and bronchial irritation.

**Warnings:**  
**Do not use:** ■ in a child under 2 years of age. ■ in a 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 an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if your child has:** ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus), or cough that lasts or is chronic such as occurs with asthma, chronic bronchitis or emphysema.

**Do not use more than the recommended dose.**

1/6 FL OZ (5 mL)  
1 Teaspoon

**KramerNovis**  
Pharmaceuticals within reach of patients

TEAR AND SQUEEZE

**Drug Facts (continued)**

**Stop use and ask a doctor if:** ■ your child gets 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 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.

Adults & Children 12 years of age and older	Take 4 teaspoons (20 mL) every 4 hours, as needed.
Children 6 to under 12 years of age	Take 2 teaspoons (10 mL) every 4 hours, as needed.
Children 2 to under 6	Take one pre-measured single dose package (1 teaspoon or 5 mL) every 4 hours, as needed.
Children under 2 years	Do not use.

**Other information:** ■ Tamper Evident. Do not use if packet is torn, cut or opened. ■ Store at controlled room temperature 15° to 30°C (59° to 86°F). ■ Avoid excessive heat or humidity.

**Inactive ingredients:** Citric acid, Flavor, Glycerin, Methylparaben, Propylene glycol, Propylparaben, Purified water, Sodium citrate and Sucralose.

**Instructions for use:** Hold package upright, bend top back and forth and tear along dotted line. To release cough medicine, squeeze bottle gently.

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Rev 08/18

**KramerNovis**  
Pharmaceuticals within reach of patients

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Lot No.

**Drugs Facts**

**Active Ingredients** (In each 5 mL tsp) **Purpose**  
Dextromethorphan HBr, USP 5 mg, Cough suppressant  
Guaifenesin, USP 75 mg, Expectorant  
Phenylephrine HCl, USP 2.5 mg, Nasal decongestant

**Uses**  
■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.  
■ temporarily relieves these symptoms occurring with cold:  
■ nasal congestion  
■ cough due to minor throat and bronchial irritation

**Warnings**  
**Do not use**  
■ in a child under 2 years of age.  
■ in a 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 an MAOI, ask a doctor or pharmacist before giving this product.

**Ask a doctor before use if your child has**  
■ heart disease ■ high blood pressure  
■ thyroid disease ■ diabetes  
■ 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 exceed the recommended dosage.

**Stop use and ask a doctor if**  
■ your child gets 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.

Exp. Date

NDC 52083-232-16

# TUSSI-PRES

**Pediatric**  
COUGH SUPPRESSANT  
EXPECTORANT  
NASAL DECONGESTANT  
ORANGE FLAVOR

**Each 5 ml (one teaspoon) contains:**  
Dextromethorphan HBr 5 mg  
Guaifenesin 75 mg  
Phenylephrine HCl 2.5 mg

✓ SUGAR FREE ✓ DYE FREE  
✓ ALCOHOL FREE ✓ SACCHARIN FREE

16 FL.oz.

MANUFACTURED IN USA FOR  
**KN KRAMER-NOVIS**  
San Juan, P.R. 00917

**Drugs 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

age	dose
adults and children 12 years and over	20mL (4 tsp) every 4 hours
children 6 years to under 12 years	10mL (2 tsp) every 4 hours
children 2 years to under 6 years	5mL (1 tsp) every 4 hours
under 2 years	do not use

**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, Glycerin, Methylparaben, Natural Flavor, Propylene 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

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## TUSSI PRES PEDIATRIC

guaifenesin, phenylephrine hcl,dextromethorphan hydrobromide syrup

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:52083-232

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	75 mg in 5 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL	
Inactive Ingredients				
Ingredient Name			Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	ORANGE (CITRUS ORANGE)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-232-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2011	07/12/2017
2	NDC:52083-232-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2011	07/12/2017
3	NDC:52083-232-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2011	
4	NDC:52083-232-05	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2012	10/31/2022
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		03/24/2011	

**Labeler** - KRAMER NOVIS (090158395)

**Registrant** - KRAMER NOVIS (090158395)

Revised: 10/2022

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