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.

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

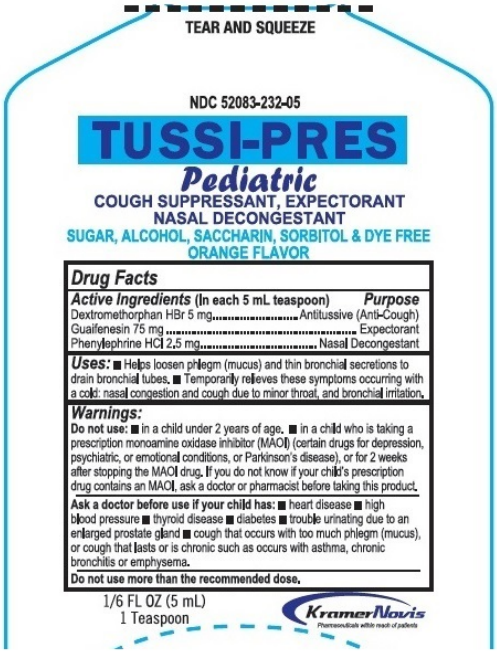
SUGAR, ALCOHOL, SACCHARIN, SORBITOL & DYE FREE

ORANGE FLAVOR

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

1 (787) 767-2072 www.kramernovis.com

Packaging



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 KRAMER NOVIS