PRESGEN 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.

PRESGEN PEDIATRIC

Drug Facts

Active Ingredients
(in each 5 ml tsp):

Dextromethorphan HBr, 5 mg

Guaifenesin 75 mg

Phenylephrine HCl, 2.5 mg

Purpose:

Cough suppressant

Expectorant

Nasal Decongestant

Uses:

• helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make cough more productive.

Temporarily relieves :

• nasal congestion due to hay fever or other upper respiratory allergies (allergic rhinitis)

• cough due to minor throat and bronchial irritation as may occur with the common cold

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 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.

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 OVER**	*20 mL (4 tsp)*
	CHILDREN 6 YEARS TO UNDER 12 YEARS	*10 mL (2 tsp)*
	CHILDREN 2 YEARS TO UNDER 6 YEARS	*5 mL (1 tsp)*
	CHILDREN UNDER 2 YEARS OF AGE	*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, Flavor, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate and Sucralose

Compare to Tussi-Pres Pediatric®

Dextromethorphan HBr

COUGH SUPPRESSANT

Guaifenesin

EXPECTORANT

Phenylephrine HCl

NASAL DECONGESTANT

SUGAR AND ALCOHOL FREE

SACCHARIN & SORBITOL FREE

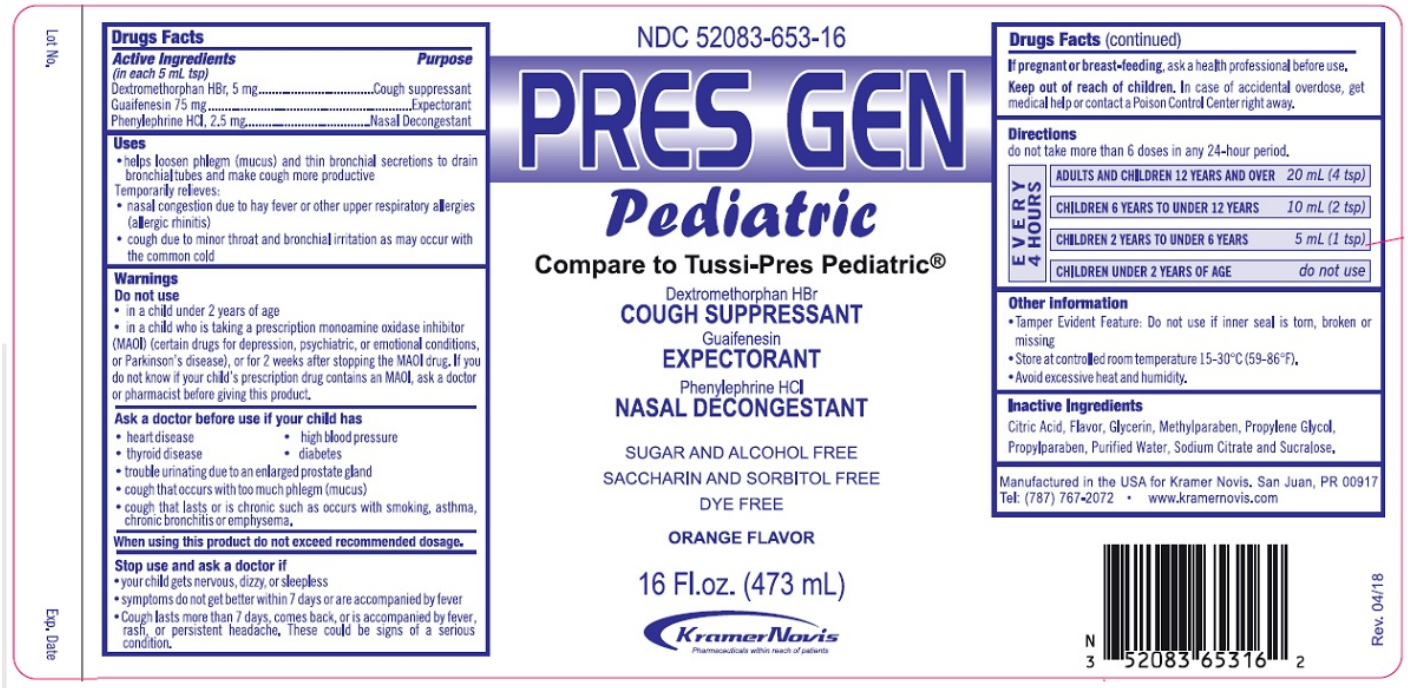
DYE FREE

ORANGE FLAVOR

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

Tel: (787) 767-2072 www.kramernovis.com

Packaging



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guaifenesin, phenylephrine hcl,dextromethorphan hydrobromide syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-653
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:52083-653-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2011	

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