

PRESGEN- guaifenesin, phenylephrine hydrochloride, 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.

DRUG FACTS

Active Ingredients per 5 ml: Guaifenesin 200 mg, Phenylephrine HCL 5 mg, Dextromethorphan HBr 10 mg

COUGH SUPPRESSANT

NASAL DECONGESTANT

EXPECTORANT

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

Do Not Use: in a child under 2 years of age

if you are 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, thyroid disease, high blood pressure, diabetes trouble urinating due to enlargement of the prostate gland

cough that occurs with too much phlegm (mucus)

chronic bronchitis or emphysema

When using this product, do not exceed recommended dosage

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

adults and children 12 years and over 10mL (2 tsp) every 4 hours

children 6 to under 12 years 5mL (1 tsp) every 4 hours

children 2 to under 6 years 2.5mL (1/2 tsp) every 4 hours

under 2 years do not use

do not take more than 6 doses in any 4 hour period

If pregnant or breast feeding, ask a health professional before use

Keep out of reach of children

Inactive Ingredients:

citric acid, red 40, glycerin, methylparaben, potassium sorbate, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Packaging

Lot No.

Drugs Facts

Active Ingredients
(in each 5 mL tsp)

Dextromethorphan HBr, USP 10 mg Cough suppressant
 Guaifenesin, USP 200 mg Expectorant
 Phenylephrine HCl, USP 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
 - cough due to minor throat and bronchial irritation

Warnings
Do not use

- in a child under 2 years of age
- 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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- thyroid disease
- 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 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.

Exp. Date

NDC 52083-632-16

PRES GEN

Compare to Tussi-Pres®

**COUGH SUPPRESSANT - EXPECTORANT
NASAL DECONGESTANT**

Dextromethorphan HBr, USP 10 mg
 Guaifenesin, USP 200 mg
 Phenylephrine HCl, USP 5 mg

**SUGAR AND ALCOHOL FREE
SACCHARIN FREE
SORBITOL FREE
CHERRY FLAVOR**

16 Fl.oz. (474 mL)



Pharmaceuticals within reach of patients

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.

EVERY 4 HOURS	ADULTS AND CHILDREN 12 YEARS AND OVER 10 mL (2 tsp)
	CHILDREN 6 TO YEARS 12 YEARS 5 mL (1 tsp)
	CHILDREN 2 YEARS TO UNDER 6 YEARS 2.5 mL (½ 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, FD&C red 40, flavor, glycerin, methylparaben, potassium sorbate, propylene glycol, propylparaben, purified water, sodium citrate and sucralose.

Manufactured in the USA for Kramer-Novis, San Juan, PR 00917.
Tel: (787) 767-2072.

Rev 03/17



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PRESGEN

guaifenesin, phenylephrine hydrochloride, dextromethorphan hydrobromide syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-632
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	

SODIUM CITRATE (UNII: 1Q73Q2JULR)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Product Characteristics

Color	red (CHERRY RED)	Score	
Shape		Size	
Flavor	CHERRY (SOUR CHERRY)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-632-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/28/2011	

Labeler - Kramer Novis (090158395)

Registrant - Kramer Novis (090158395)