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

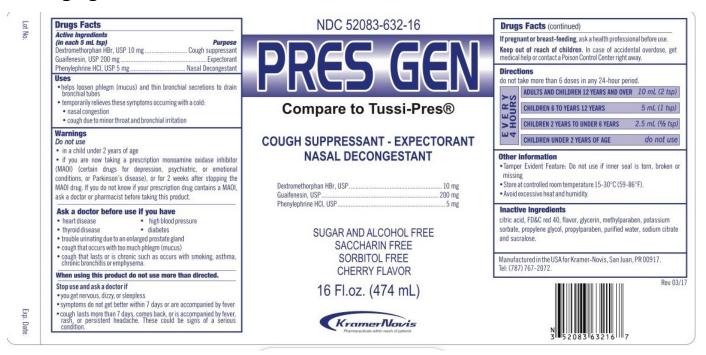
symptoms do not get better within 7 days or are accompanied by fever cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition adults and children 12 years and over 10mL (2 tsp) every 4 hours

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



PRESGEN

guaifenesin, phenylephrine hydrochloride, dextromethorphan hydrobromide syrup

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:520	83-632	
Route of Administration	ORAL					
Active Ingredient/Active	Moiety	Active Ingredient/Active Moiety				
lus as see a						
ingred	lient Name		Basis of Str	ength	Strength	
GUAIFENESIN (UNII: 495W7451VQ)		7451VQ)	Basis of Str	ength	Strength 200 mg in 5 mL	

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	10 mg
(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 5 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
GLYCERIN (UNII: PDC6A3C0OX)			
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (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			

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		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)

Revised: 10/2022 Kramer Novis