

PRESGEN B - dextromethorphan hydrobromide, brompheniramine maleate, phenylephrine hydrochloride 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® B

Drug Facts

Active Ingredients (in each 5 mL tsp)

- Brompheniramine Maleate, 4 mg
- Dextromethorphan HBr, 20 mg
- Phenylephrine HCl, 10 mg

Purposes

- Antihistamine
- Cough Suppressant
- Nasal Decongestant

Uses: Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • sneezing • itchy nose or throat • runny nose • itchy, watery eyes • nasal congestion • temporarily controls cough due to minor throat and bronchial irritation associated with inhaled irritants • temporarily restores freer breathing through nose

Warnings: 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 • high blood pressure • thyroid disease • diabetes • glaucoma • cough that occurs with too much phlegm (mucus) • trouble urinating due to an enlarged prostate gland • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema. **Do not** give this product to children who have breathing problems such as chronic bronchitis or who have glaucoma without first consulting child's doctor.

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

While using this product:

- **do not exceed recommended dosage** • excitability may occur especially in children • drowsiness may occur; alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Use caution when driving a motor vehicle or operating machinery.

Stop use and ask a doctor if:

- you get nervous, dizzy or sleepless • new symptoms occur • symptoms do not get better within 7 days or are accompanied by fever • coughs lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of serious conditions.

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

EVERY 4 HOURS	Adults and Children 12 years of age and over	5mL (1 tsp)
	Children 6 years to under 12 years	2.5 mL (1/2 tsp)
	Children under 6 years	consult physician

Children under 2 years

do not use

Other information: • Tamper evident: 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 or humidity

Inactive ingredients: Citric acid, flavor, hydroxyethylcellulose, methylparaben, propylene glycol, propylparaben, purified water and sucralose

Compare to Tussi- Pres B®

Brompheniramine Maleate
ANTI HISTAMINE

Dextromethorphan HBr
COUGH SUPPRESSANT

Phenylephrine HCl
NASAL DECONGESTANT

SUGAR AND ALCOHOL FREE
SACCHARINE FREE
DYE FREE

GRAPE FLAVOR

Manufactured in the USA for Kramer Novis. San Juan, Puerto Rico 00917 Tel.787-767-2072
www.kramernovis.com

Packaging

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NDC 52083-637-16

PRESGEN[®]B

Compare to Tussi-Pres B®

Brompheniramine Maleate
ANTI HISTAMINE

Dextromethorphan HBr
COUGH SUPPRESSANT

Phenylephrine HCl
NASAL DECONGESTANT

SUGAR AND ALCOHOL FREE
SACCHARIN FREE
DYE FREE
GRAPE FLAVOR

16 Fl. Oz. (473mL)

KramerNovis
Pharmaceuticals within reach of patients

Drug Facts (continued)									
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Manufactured in the USA for Kramer Novis, San Juan, Puerto Rico 00917 Tel.787-767-2072 www.kramernovis.com Rev. 11/18									



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Lot No.
Exp Date.

PRESGEN B

dextromethorphan hydrobromide, brompheniramine maleate, phenylephrine hydrochloride syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-637
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G1P2FN)		BROMPHENIRAMINE MALEATE	4 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYDROXYETHYL CELLULOSE (1500 MPAS AT 1%) (UNII: L605B5892V)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE (SWEET GRAPE)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-637-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/29/2011	

Labeler - KRAMER NOVIS (090158395)**Registrant** - KRAMER NOVIS (090158395)