

**TUSSI PRES 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.*

-----

**TUSSI PRES- 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 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 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 the 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:**

• if you get nervous, dizzy or sleepless • new symptoms occur • 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 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

<b>EVERY 4 HOURS</b>	Adults and Children 12 years of age and over	5mL (1tsp)
	Children 6 years to under 12 years	2.5mL (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 excess heat or humidity

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

Brompheniramine Maleate

**ANTI-HISTAMINE**

Dextromethorphan HBr

**COUGH SUPPRESSANT**

Phenylephrine HCl

**NASAL DECONGESTANT**

SUGAR AND ALCOHOL FREE

SACCHARIN FREE

DYE FREE

**GRAPE FLAVOR**

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

[www.kramernovis.com](http://www.kramernovis.com)

**Packaging**

<b>Drug Facts</b>	
<b>Active Ingredients</b> (in each 5 mL tsp)	<b>Purposes</b>
Brompheniramine Maleate, 4 mg.....	Antihistamine
Dextromethorphan HBr, 20 mg.....	Cough Suppressant
Phenylephrine HCl, 10 mg.....	Nasal Decongestant
<b>Uses:</b> 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	
<b>Warnings: Do not use</b>	
■ 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.	
<b>Ask a doctor before use if you have:</b>	
■ 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 the child's doctor.	
<b>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</b>	
<b>While using this product:</b>	
■ 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.	

NDC 52083-237-16

# TUSSI PRES-B

with Brompheniramine

**Brompheniramine Maleate**  
**ANTIHISTAMINIC**

**Dextromethorphan HBr**  
**COUGH SUPPRESSANT**

**Phenylephrine HCl**  
**NASAL DECONGESTANT**

**SUGAR AND ALCOHOL FREE**

**SACCHARIN FREE-DYE FREE**

**GRAPE FLAVOR**

**16 Fl. Oz. (473mL)**



<b>Drug Facts</b> (continued)		
<b>Stop use and ask a doctor if:</b>		
■ 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.		
<b>If pregnant or breast-feeding</b> ask a health professional before use. <b>KEEP OUT OF REACH OF CHILDREN.</b> In case of overdose, get medical help or contact a Poison Control Center right away		
<b>Directions</b> do not take more than 6 doses in any 24-hour period		
<b>EVERY 4 HOURS</b>	Adults and Children 12 years of age and over	5 mL (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
<b>Other information:</b> ■ 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		
<b>Inactive ingredients:</b> Citric acid, flavor, hydroxyethylcellulose, methylparaben, propylene glycol, propylparaben, purified water and sucralose		
Manufactured in the USA for Kramer Novis, San Juan, Puerto Rico 00917 Tel.787-767-2072 www.kramernovis.com		
Rev. 11/18		



Lot No.  
Exp Date.

## TUSSI PRES B

dextromethorphan hydrobromide, brompheniramine maleate, phenylephrine hydrochloride syrup

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52083-237
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
<b>BROMPHENIRAMINE MALEATE</b> (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	4 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

### Inactive Ingredients

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

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE (SWEET GRAPE)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-237-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2011	
2	NDC:52083-237-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2011	
3	NDC:52083-237-16	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 NO VIS (090158395)**Registrant** - KRAMER NO VIS (090158395)

Revised: 10/2019

KRAMER NO VIS