

# **TUSSI PRES- 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.*

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## **TUSSI-PRES**

### **Drug Facts**

#### ***Active Ingredients (in each 5mL tsp)***

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

#### ***Purposes***

Cough suppressant

Expectorant

Nasal decongestant

#### ***Uses***

- 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

#### ***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
- 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**

- 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.

**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

<b>EVERY 4 HOURS</b>	<b>ADULTS AND CHILDREN 12 YEARS AND OVER</b>	10 mL (2 tsp)
	<b>CHILDREN 6 YEARS TO UNDER 12 YEARS</b>	5 mL (1 tsp)
	<b>CHILDREN 2 YEARS TO UNDER 6 YEARS</b>	2.5 mL (1/2 tsp)
	<b>CHILDREN UNDER 2 YEARS OF AGE</b>	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.

Dextromethorphan HBr

**COUGH SUPPRESSANT**

Guaifenesin

**EXPECTORANT**

Phenylephrine HCl

**NASAL DECONGESTANT**

SUGAR, ALCOHOL, SACCHARIN & SORBITOL FREE

**CHERRY FLAVOR**

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

Tel: (787) 767-2072

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

**Packaging**



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

NDC 52083-231-16

# TUSSI-PRES

Dextromethorphan HBr  
**COUGH SUPPRESSANT**  
Guaifenesin  
**EXPECTORANT**  
Phenylephrine HCl  
**NASAL DECONGESTANT**

SUGAR, ALCOHOL, SACCHARIN & SORBITOL FREE  
CHERRY FLAVOR

16 Fl.oz. (473 mL)



Drug Facts	
Active Ingredients (in each 5mL tsp)	Purposes
Dextromethorphan HBr 10 mg.....	Cough suppressant
Guaifenesin 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Nasal decongestant

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Drug Facts (continued)	
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• Avoid excessive heat or humidity	
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Manufactured in the USA for Kramer-Novis, San Juan, PR 00917 Tel. (787) 767-2072 <a href="http://www.kramernovis.com">www.kramernovis.com</a>	



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Rev. 07/18

**TUSSI PRES**

guaifenesin, phenylephrine hydrochloride, dextromethorphan hydrobromide syrup

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52083-231
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	red (CHERRY RED)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (SOUR CHERRY)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-231-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2011	
2	NDC:52083-231-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2011	07/12/2017
3	NDC:52083-231-10	10 mL in 1 PACKET; Type 0: Not a Combination Product	03/28/2011	

## Marketing Information

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

**Labeler** - Kramer Novis (090158395)

**Registrant** - Kramer Novis (090158395)

Revised: 12/2018

Kramer Novis