# TUSSI PRES- guaifenes in, 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.

-----

#### **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

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

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

### **Packaging**



NDC 52083-231-10

COUGH SUPPRESSANT, EXPECTORANT NASAL DECONGESTANT CHERRY FLAVOR

#### Drug Facts

## Active Ingredients

Purpose

(In each 5 mL teaspoon) Dextromethorphan HBr 10 mg. Guaifenesin 200 mg..... Phenylephrine HCl 5 mg

.Cough Suppressant

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: m in a child under 2 years of age m if you are now taking a prescription monoamine coldase 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: m heart disease m high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland • cough that occurs with too much philegm (mucus) • cough that lasts or is chronic such as occurs with smoking, shma, chronic bronchitis or emphysema.

hen using this product do not use more than directed.

1/3 FL OZ (10 mL) 2 Teaspoons



# BEND HERE TEAR AND SQUEEZE

#### Drug Facts (continued)

Stop use and ask a doctor if: w you get nervous, dizzy or sleeples symptoms do not get better within 7 days or are accompanied by feve
 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 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.

the USA f Adults & Children 12 years of age and older Manufactured in the is. San Juan, PR 0 www.kramemo

767-207.

Take one pre-measured single dose package (2 leaspoons or 10 mL) every 4 hours, as needed.

Children 6 to under 12 years of age Children 2 to under 6

Measure out and take only 1 leaspoon (5 mL) every 4 hours, as needed. Measure out and take only 1/2 tsp (2.5 mL) every 4 hours, as needed.

Children under 2 years Do not use

Other Information: Tamper Evident. Do not use if packet is torn cut or opened. 

Store at controlled room temperature 15' to 30°C (59 to 86°F). 

Avoid excessive heat or humidity.

Inactive Ingredients: ciric acid, FD & C red 40, flavor, glycerin methylparaben, potassium sorbate, propylene glycol, propylparabe purified water, sodium citrate and sugralose

Rev 03/17



#### **Drug Facts**

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

orphan HBr 10 mg.\_ ..Cough suppressan ....Expectoran henvlephrine HCI 5 mg ..Nasal decongestant

• helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

mporarily relieves these symptoms occurring with cold:

cough due to minor throat and bronchial irritation

Do not use: in a child under 2 years of age

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 • diahetes
- · trouble urinating due to an enlarged prostate gland cough that occurs with too much phlegm (mucus)
- $\bullet$  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
- cough lasts more than 7 days, comes back, or is accompanie by fever, rash, or persistent headache. These could be signs of a serious condition.

NDC 52083-231-16

Dextromethorphan HBr

COUGH SUPPRESSANT

Guaifenesin

**EXPECTORANT** 

Phenylephrine HCI

NASAL DECONGESTANT

SUGAR, ALCOHOL, SACCHARIN & SORBITOL FREE **CHERRY FLAVOR** 

16 Fl.oz. (473 mL)



#### Drug 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

ke more than 6 doses in any 24-hour period

ш	100000		
ı		ADULTS AND CHILDREN 12 YEARS AND OVER	10 mL (2 tsp)
ı	~ %		
ı	25	CHILDREN 6 YEARS TO UNDER 12 YEARS	5 mL (1 tsp)
ı			
ı	>Ĭ	CHILDREN 2 YEARS TO UNDER 6 YEARS	2.5 mL (1/2 tsp)
	Lifet		
١	_~	CHILDREN UNDER 2 YEARS OF AGE	do not use

#### Other information

- Tamper evident feature. Do not use if inner seal is torn, broke • Tamper evident leadine. Do not use it littler seat is confi, bloor missing.
  • Store at controlled room temperature 15-30°C (59-86°F)
  • Avoid excessive heat or humidity

## Inactive ingredients

Citric acid, FD&C Red 40, flavor, glycerin, methylparaben ootassium sorbate, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.

Manufactured in the USA for Kramer-Novis, San Juan, PR 0091



guaifenesin, phenylephrine hydrochloride, dextromethorphan hydrobromide syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-231
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	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL	
<b>DEXTRO METHO RPHAN HYDRO BRO MIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

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

	Packaging			
:	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	NDC:52083-231-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2011	
l	NDC:52083-231-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2011	07/12/2017
	NDC:52083-231-10	10 mL in 1 PACKET; 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: 12/2018 Kramer Novis