

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.

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

EVERY 4 HOURS	ADULTS AND CHILDREN 12 YEARS AND OVER	10 mL (2 tsp)
	CHILDREN 6 YEARS TO UNDER 12 YEARS	5 mL (1 tsp)
	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 52083-231-16

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

Uses
 • helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
 • temporarily relieves these symptoms occurring with cold:
 • nasal congestion
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Ask a doctor before use if you have
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 • thyroid disease • diabetes
 • trouble urinating due to an enlarged prostate gland
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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 (continued)

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Directions
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Rev. 07/18

TUSSI PRES

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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
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	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	10/31/2022

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