

**TUSICOF- guaifenesin, phenylephrine hcl, dextromethorphan tablet, coated  
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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**TUSICOF®**

**Drug Facts**

***Active Ingredients (in each caplet)***

Dextromethorphan HBr, 20 mg

Guaifenesin, 400 mg

Phenylephrine HCl, 10 mg

***Purpose***

Cough suppressant

Expectorant

Nasal Decongestant

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
  - nasal congestions
  - cough due to minor throat and bronchial irritation

**Warnings**

**Do not use** 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**

- diabetes • heart disease • thyroid disease • high blood pressure
- 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 dose.**

**Stop use and ask a doctor if**

- symptoms do not improve • new symptoms occur
- redness or swelling is present
- nervousness, dizziness or sleeplessness occur
- symptoms do not improve within 7 days or are accompanied by fever
- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash or a persistent headache. A persistent cough may be a sign 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

### **Directions**

Adults and children 12 years of age or older: Take 1 caplet every 4 hours as needed, do not exceed 6 caplets in 24 hours, or as directed by a doctor.

Children under 12 years: consult a doctor.

### **Other Information**

- Tamper evident feature: Do not use if packet is torn, cut or open.
- Store at controlled room temperature 15-30°C (59-86°F).
- Avoid excessive heat and humidity.

### **Inactive Ingredients**

Hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Dextromethorphan HBr

COUGH SUPPRESSANT

Guaifenesin

EXPECTORANT

Phenylphrine HCL

NASAL DECONGESTANT

**SUGAR & DYE FREE**

Manufactured in the USA for Kramer Novis

San Juan, PR 00917. Tel: (787) 767-2072

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

### **Packaging**

NDC 52083-289-02

*Physician's Sample*  
Highest concentration per caplet available

# TUSICOF<sup>®</sup>

## Caplets



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

**SUGAR & DYE FREE**

www.kramernovis.com

  
*Pharmaceuticals with reach of patients*

Net Contents: 2 Caplets


Drug Facts	
<b>Active Ingredients (in each caplet)</b>	<b>Purpose</b>
Dextromethorphan HBr, 20 mg.....	Cough Suppressant
Guaifenesin, 400 mg.....	Expectorant
Phenylephrine HCl, 10 mg.....	Nasal Decongestant
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes</li> <li>• temporarily relieves these symptoms occurring with a cold:               <ul style="list-style-type: none"> <li>• nasal congestions</li> <li>• cough due to minor throat and bronchial irritation</li> </ul> </li> </ul>	
<b>Warnings</b>	
<p><b>Do not use</b> 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 the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>• diabetes</li> <li>• heart disease</li> <li>• thyroid disease</li> <li>• high blood pressure</li> <li>• trouble urinating due to an enlarged prostate gland</li> <li>• cough that occurs with too much phlegm (mucus)</li> <li>• cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema</li> </ul>	
<b>When using this product do not exceed recommended dose.</b>	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>• symptoms do not improve</li> <li>• new symptoms occur</li> <li>• redness or swelling is present</li> <li>• nervousness, dizziness or sleeplessness occur</li> <li>• symptoms do not improve within 7 days or are accompanied by fever</li> <li>• cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash or a persistent headache. A persistent cough may be a sign of a serious condition.</li> </ul>	
<p><b>If pregnant or breast-feeding</b>, ask a health professional before use. <b>Keep out of reach of children.</b> In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p>	
<b>Directions</b>	<b>Other Information</b>
<p>Adults and children 12 years of age or older: Take 1 caplet every 4 hours as needed, do not exceed 6 caplets in 24 hours, or as directed by a doctor.</p> <p>Children under 12 years: consult a doctor.</p>	<ul style="list-style-type: none"> <li>• Tamper evident feature: Do not use if packet is torn, cut or open.</li> <li>• Store at controlled room temperature 15-30°C (59-86°F).</li> <li>• Avoid excessive heat or humidity.</li> </ul>
<b>Inactive Ingredients</b>	
<p>Hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid</p>	<p>Manufactured in the USA for Kramer Novis San Juan, PR 00917. Tel: (787) 767-2072 www.kramernovis.com</p>
Rev 08/18	

NDC 52083-289-60

Highest concentration per caplet available

# TUSICOF<sup>®</sup>

## Caplets




COUGH SUPPRESSANT  
EXPECTORANT  
NASAL DECONGESTANT

Dextromethorphan HBr .....20mg  
Guaifenesin .....400mg  
Phenylephrine HCl .....10mg

**SUGAR & DYE FREE**

www.kramernovis.com  
*Pharmaceuticals with reach of patients*

Net Contents: 60 Caplets

<b>Drug Facts</b>	<p><b>Active Ingredients (in each caplet)</b></p> <p>Dextromethorphan HBr, 20 mg.....Cough Suppressant Guaifenesin, 400 mg.....Expectorant Phenylephrine HCl, 10 mg.....Nasal Decongestant</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes</li> <li>• temporarily relieves these symptoms occurring with a cold:               <ul style="list-style-type: none"> <li>• nasal congestion</li> <li>• cough due to minor throat and bronchial irritation</li> </ul> </li> </ul> <p><b>Warnings</b></p> <p><b>Do not use</b> 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 the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>• diabetes</li> <li>• heart disease</li> <li>• thyroid disease</li> <li>• high blood pressure</li> <li>• trouble urinating due to an enlarged prostate gland</li> <li>• cough that occurs with too much phlegm (mucus)</li> <li>• cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema</li> </ul> <p><b>When using this product do not exceed recommended dose.</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• symptoms do not improve</li> <li>• new symptoms occur</li> <li>• redness or swelling is present</li> <li>• nervousness, dizziness or sleeplessness occur</li> <li>• symptoms do not improve within 7 days or are accompanied by fever</li> <li>• cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or a persistent headache. A persistent cough may be a sign of a serious condition.</li> </ul> <p><b>If pregnant or breast-feeding</b>, ask a health professional before use. <b>Keep out of reach of children.</b> In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p><b>Directions</b></p> <p>Adults and children 12 years of age and older: Take 1 caplet every 4 hours as needed, do not exceed 6 caplets in 24 hours, or as directed by a doctor.</p> <p>Children under 12 years: consult a doctor.</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• Tamper evident feature: Do not use if inner seal is torn, broken or missing.</li> <li>• Store at controlled room temperature 15-30°C (59-86°F).</li> <li>• Avoid excessive heat or humidity.</li> </ul> <p><b>Inactive ingredients</b> hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, xanthan gum</p> <p>Manufactured in the USA for Kramer Novis, San Juan, PR 00917. Tel: (787) 767-2072. www.kramernovis.com</p>
 N 3 52083-28960 6 03/17	

## TUSICOF

guaifenesin, phenylephrine hcl, dextromethorphan tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-289
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MALTO DEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	white (snow white)	<b>Score</b>	2 pieces
<b>Shape</b>	CAPSULE (T)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	T
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-289-02	2 in 1 PACKET; Type 0: Not a Combination Product	07/18/2012	
2	NDC:52083-289-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2012	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/18/2012	

**Labeler** - Kramer Novis. (090158395)

Revised: 12/2018

Kramer Novis.