

**TUSSNEX FM SEVERE COUGH AND CONGESTION- dextromethorphan hbr,  
guaifenesin, phenylephrine hcl liquid  
Guardian Drug Company**

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**Maximum strength Tussnex FM Severe cough and congestion**

**Active ingredients (in each 20 mL)**

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 and make coughs more productive
- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help you get to sleep
- nasal congestion due to a cold

**Warnings**

**Do not use**

- for children under 12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for 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
- persistent or chronic cough such as occurs with smoking, asthma, chronic

bronchitis or emphysema

- cough that occurs with too much phlegm (mucus)

When using this product

- do not use more than directed

*Stop use and ask a doctor if*

- nervousness, dizziness or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- cough comes back, or occurs with 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 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- Adults and children 12 years and older: 20 mL in dosing cup provided every 4 hours
- Children under 12 years of age: Do not use

### **Other information**

- each 20 mL contains: sodium 20 mg
- store between 15-30°C(59-86°F)
- do not refrigerate
- dosing cup provided

### **Inactive ingredients**

citric acid anhydrous, edetate disodium, FD and C blue 1, FD and C red 40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

### **PDP**

compare to the active ingredients in Mucinex Fast Max Severe Cough and congestion

Maximum strength Tussnex FM

Severe Cough and Congestion

Dextromethorphan HBr

Cough Suppressant

Guaifenesin

Expectorant

Phenylephrine HCl

Nasal Decongestant

Relieves:

Soothes cough

Thins and loosens mucus

Relieves Nasal and chest congestion

For ages 12 and over



**Drug Facts**

**Active ingredients (in each 20 mL) Purpose**  
 Dextromethorphan HBr 20 mg.....Cough suppressant  
 Guaifenesin 400 mg.....Expectorant  
 Phenylephrine HCl 10 mg.....Nasal decongestant

**Uses** ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive  
 ■ temporarily relieves: • cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants • the intensity of coughing  
 • the impulse to cough to help you get to sleep • nasal congestion due to a cold

**PEEL HERE FOR CONTINUED DRUG FACTS** ▶

**TAMPER EVIDENT: DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING**  
 \*This product is not manufactured or distributed by Reckitt Benckiser, the distributor of Mucinex® Fast Max™ Severe Congestion and Cough.



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MFR# 53041 REV 0314

**Guardian Drug Company**  
 2 Charles Court  
 Dayton, NJ 08810

**Drug Facts (continued)**

**Warnings**  
**Do not use** ■ for children under 12 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 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  
 ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema  
 ■ cough that occurs with too much phlegm (mucus)

**When using this product**  
 ■ do not use more than directed

**Stop use and ask a doctor if**  
 ■ nervousness, dizziness or sleeplessness occur  
 ■ symptoms do not get better within 7 days or occur with fever  
 ■ cough comes back, or occurs with 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. ▶

**Drug Facts (continued)**

**Directions**  
 ■ do not take more than 6 doses in any 24-hour period  
 ■ measure only with dosing cup provided  
 ■ do not use dosing cup with other products  
 ■ dose as follows or as directed by a doctor  
 ■ **Adults and children 12 years and older:** 20 mL in dosing cup provided every 4 hours.  
 ■ **Children under 12 years of age:** Do not use.

**Other information**  
 ■ each 20 mL contains: sodium 20 mg  
 ■ store between 15-30°C (59-86°F)  
 ■ do not refrigerate  
 ■ dosing cup provided

**Inactive ingredients** citric acid anhydrous, edetate disodium, FD&C blue #1, FD&C red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum.

# TUSSNEX FM SEVERE COUGH AND CONGESTION

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53041-617
<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 20 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53041-617-58	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2012	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/01/2012	

**Labeler** - Guardian Drug Company (119210276)

**Registrant** - Guardian Drug Company (119210276)

### Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	manufacture(53041-617)

Revised: 12/2024

Guardian Drug Company