

**TUSSNEX FM COLD, FLU AND SORE THROAT- acetaminophen,  
dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid  
Guardian Drug Company**

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**Maximum Strength Tussnex FM cold, flu and sore throat**

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

**Acetaminophen 650 mg**

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

**Purpose**

**Pain reliever/fever reducer**

Cough suppressant

Expectorant

Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and minor bronchial irritation
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- temporarily promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

**Warnings**

- **Liver warning:** This product contains acetaminophen. severe liver damage may occur if you take:
  - more than 6 doses in 24 hours, which is maximum daily amount
  - with other drugs containing acetaminophen
  - 3 or more alcoholic drinks daily while using this product
- **Sore throat warning:** if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

## Do not use

- **with any other drug containing acetaminophen** (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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

- liver disease
- 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)

*Ask a doctor or pharmacist before use if*

- you are taking the blood thinning drug warfarin

## When using this product

- **do not use more than directed**

## Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a poison control center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## Directions

- do not take more than directed (see overdose warning)
- 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 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 Cold, Flu and Sore throat

Maximum strength Tussnex FM

Cold, Flu and Sore throat

Acetaminophen

Pain reliever / Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Guaifenesin

Expectorant

Phenylephrine HCl

Nasal Decongestant

Calms headache and fever

Soothes cough

Thins and loosens mucus

Relieves Nasal and chest congestion

For ages 12 and over

\*Compare to the active ingredients  
in Mucinex® Fast-Max™  
Cold, Flu & Sore Throat  
NDC 53041-618-58

**GUARDIAN**

Maximum Strength

**Tussnex FM**

**Cold, Flu & Sore Throat**

**ACETAMINOPHEN**

Pain Reliever/ Fever Reducer

**Dextromethorphan HBr**

Cough Suppressant

**Guaifenesin**

Expectorant

**Phenylephrine HCl**

Nasal Decongestant

**Multi-Symptom**

- Calms Headache & Fever
- Sothes Cough • Thins & Loosens Mucus
- Relieves Nasal & Chest Congestion

**For ages 12  
& over**

**6 FL OZ (177 mL)**

**Drug Facts**

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

Acetaminophen 650 mg.....Pain reliever/fever reducer  
Dextromethorphan HBr 20 mg.....Cough suppressant  
Guaifenesin 400 mg.....Expectorant  
Phenylephrine HCl 10 mg.....Nasal decongestant

**Uses** temporarily relieves these common cold and flu symptoms: ■ nasal congestion ■ sinus congestion and pressure ■ cough due to minor throat and bronchial irritation ■ minor aches and pains ■ sore throat ■ headache ■ temporarily reduces fever ■ temporarily promotes nasal and/or sinus drainage ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

**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™ Cold, Flu and Sore Throat.



MFR# 53041 REV 0314

Guardian Drug Company  
2 Charles Court  
Dayton, NJ 08810

**Drug Facts (continued)**

**Warnings**

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**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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**

- liver disease ■ 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)

**Ask a doctor or pharmacist before use if**

- you are taking the blood thinning drug warfarin

**When using this product**

- do not use more than directed

**Stop use and ask a doctor if**

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days

**Drug Facts (continued)**

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- do not take more than directed (see Overdose warning)
- 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 COLD, FLU AND SORE THROAT**

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53041-618
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<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:53041-618-58	177 mL in 1 CARTON; 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(53041-618)

Revised: 12/2024

Guardian Drug Company