

**SAFETUSSIN MAX STRENGTH MS COUGH, COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, and guaifenesin tablet**  
**KRAMER LABORATORIES**

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**SAFETUSSIN MS Cough, Cold & Flu**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant

**Uses**

- temporarily relieves common cold and flu symptoms:
- cough
- sore throat
- headache
- minor aches and pains
- fever
- helps loosen phlegm (mucus) and thin bronchial secretions to get rid the bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4000mg of acetaminophen in 24 hours, which is the maximum daily amount for this product in 24 hours
- taken with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy Alert:** Acetaminophen may cause severe skin reactions.

Symptoms may include:

- Skin reddening
- Blisters
- Rash

If a skin reaction occurs, stop use and seek medical help right away

**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.
- 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.
- If you have ever had an allergic reaction to this product or any of its ingredients
- In children under 12 years of age

### **Ask a doctor before use if you have**

- liver disease
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema

### **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 as directed

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain 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 headache that lasts.

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.**

### **Directions**

- do not use more than directed.

adults & children 12 years & over	Take 2 caplets every 4 hours (do not take more than 12 caplets in 24 hours)
children under 12 years of age	do not use

### **Other information**

- ◦ store at 15°-30°C (59° - 86°F).
- Keep this carton for future reference on full labeling.

### **Inactive ingredients**

Crospovidone, flavor, Hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, stearic acid, sucralose.

### **Questions or comments**

**1-866-467-2748**

### **PRINCIPAL DISPLAY PANEL - 236 ml Bottle Label**

SAFE FOR ADULTS WITH HIGH BLOOD PRESSURE & DIABETES

NDC 55505-230-24

**Safetussin®**

**MAX STRENGTH**

**MULTI-SYMPTOM**

**Cough, Cold & Flu**

**Acetaminophen / Pain Reliever**

Dextromethorphan HBr / Cough Suppressant

Guaifenesin / Expectorant

Safe for adults with

High Blood Pressure

Diabetes

Relieves

- Headache
- Fever
- Sore Throat
- Body Aches & Pains
- Chest Congestion
- Cough

Safetussin® contains:

No decongestants

No Sugar

No Alcohol

No sorbitol

No fructose

No gluten

No dyes

SUGAR & DECONGESTANT FREE

24 Caplets

Always read and follow label directions. Do not use longer than 7 consecutive days unless directed by a doctor. Ask a doctor if you have individual health questions.

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**SAFETUSSIN MAX STRENGTH MS COUGH, COLD AND FLU**  
acetaminophen, dextromethorphan hydrobromide, and guaifenesin tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55505-230
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSPROVIDONE (120 .MU.M)</b> (UNII: 68401960MK)	
<b>HYPROMELLOSE 2208 (100 MPA.S)</b> (UNII: B1QE5P712K)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL (Caplet)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-230-24	24 in 1 CARTON; Type 0: Not a Combination Product	05/17/2024	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	05/17/2024	

**Labeler** - KRAMER LABORATORIES (122720675)

## Establishment

Name	Address	ID/FEI	Business Operations
RARITAN PHARMACEUTICALS INCORPORATED		127602287	manufacture(55505-230)

Revised: 12/2025

KRAMER LABORATORIES