

**SAFETUSSIN HIGH BLOOD PRESSURE AND DIABETES COUGH, COLD AND FLU-
acetaminophen, dextromethorphan hydrobromide, and guaifenesin liquid
KRAMER LABORATORIES**

SAFETUSSIN High Blood Pressure Nighttime COLD & FLU

Drug Facts

<i>Active ingredients (in each 30 mL dose cup)</i>	<i>Purpose</i>
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant

Uses

temporarily relieves common cold/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 6 doses in 24 hours, which is the maximum daily amount for this product
- 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 take more than directed

- do not take more than 6 doses in any 24-hours period
- measure only with dosing cup provided
- dose as follows or as directed by a doctor

adults & children 12 years & older	30 mL per dose every 4 hours
children under 12 years of age	do not use

Other information

- **each 30 mL contains:** sodium 19 mg
- store at room temperature. Do not refrigerate.

Inactive ingredients

Anhydrous citric acid, edetate disodium, flavor, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sucralose, xanthan gum.

Distributed by

PRINCIPAL DISPLAY PANEL - 236 ml Bottle Label

SAFE FOR ADULTS WITH HIGH BLOOD PRESSURE & DIABETES

NDC 55505-217-36

Safetussin®

MAX STRENGTH

MULTI-SYMP TOM

Cough, Cold & Flu

Acetaminophen / Pain Reliever 650 mg

Dextromethorphan HBr / Cough Suppressant 20 mg

Guaifenesin / Expectorant 400 mg

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

Pharmacist Recommended Brand

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.

8 FL OZ (237 mL)

Questions? Comments? Call 1-800-824-4894

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SAFETUSSIN HIGH BLOOD PRESSURE AND DIABETES COUGH, COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, and guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55505-217
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-217-36	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/17/2023	

Labeler - KRAMER LABORATORIES (122720675)

Revised: 12/2023

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