

SAFETUSSIN DM - dextromethorpan guaifenesin liquid
Kramer Laboratories

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.

Drug Facts

Active ingredients (in each 5ml tsp)	Purpose
Dextromethorphan HBr, USP 10 mg	Cough Suppressant
Guaifenesin, USP 100 mg	Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation
- loosens phlegm (mucus)
- helps rid bronchial passages of phlegm (mucus)

Warnings

Do not use 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

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

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, 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 any 24-hour period
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	2 teaspoons every 4 hours
children under 12 years	do not use

Other information:

- Protect from excessive heat and freezing. Store at 15° - 30° C (59° - 86° F)
- Phenylketonurics: each teaspoon contains phenylalanine 4.2 mg

Save this package for complete information

Inactive ingredients: aspartame, benzoic acid, citric acid, glycerin, menthol, methylparaben, natural peppermint flavor, propylene glycol, propylparaben, purified water

PRINCIPAL DISPLAY PANEL

Safetussin® DM
DAY TIME COUGH RELIEF

COUGH SUPPRESSANT/EXPECTORANT

Relieves Cough
Loosens Mucus

SAFE For Those With:
High Blood Pressure
Diabetes

SUGAR FREE

- **Dye Free**
- **Gluten Free**
- **Alcohol Free**

4 FL. OZ (120 ml.)

Safetussin® DM

Alivia la tos
Descongestiona el Pecho

SEGURO para los que padecen de:
Presión alta
Diabetes

SIN AZÚCAR

- **Sin Colorantes**
- **Sin Gluten**
- **Sin Alcohol**

4 FL. OZ (120 ml.)

NON-DROWSY

Safe Cough Relief
Pure and Simple

Safetussin® was developed by a pharmacist who recognized the special needs of many of his customers afflicted with high blood pressure, diabetes, and those looking for simple, safe cough relief.

Safetussin is specially formulated, free of alcohol, sugar, dyes, decongestants and other unwanted ingredients that are not needed for safe, adult strength cough treatment.

The Clear Choice!

Pharmacist Recommended

Dosage Cup Included
Vaso Dosificador Incluido

Distributed by/ Distribuido por
KRAMER
CONSUMER HEALTHCARE
A division of Kramer Laboratories

www.safetussin.com
www.kramerconsumerhealthcare.com

Coral Gables, FL 33134
1-800-824-4894

k0916

COUGH SUPPRESSANT / EXPECTORANT

DM DAY TIME COUGH RELIEF

Safe tussin

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL ON CAP IS BROKEN, TORN OR MISSING

Drug Facts

Active Ingredients

(in each 5ml tsp) Purpose
Dextromethorphan HBr, Cough Suppressant
USP 10 mg
Guaifenesin, USP 100 mg Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation
loosens phlegm (mucus)
helps rid bronchial passages of phlegm (mucus)

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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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Table with 2 columns: age, dose. Rows: adults and children 12 years and over (2 teaspoons every 4 hours), children under 12 years (do not use)

Other information:

- Protect from excessive heat and freezing. Store at 15° - 30° C (59° - 86° F)
Phenylephrine: each teaspoon contains phenylephrine 4.2 mg
Save this package for complete information

NON-DROWSY

Safe Cough Relief Pure and Simple

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The Clear Choice!

Pharmacist Recommended

Dosage Cup Included Vaso Dosificador Incluido

Drug Facts (continued)

Inactive Ingredients: aspartame, benzoic acid, citric acid, glycerin, menthol, methylparaben, natural peppermint flavor, propylene glycol, propylparaben, purified water

Safe tussin

DM DAY TIME COUGH RELIEF COUGH SUPPRESSANT / EXPECTORANT

Safe tussin

DM ALIVIA LA TOS DURANTE EL DIA ANTITUSIVO / EXPECTORANTE

Relieves Cough Loosens Mucus

SAFE For Those With:

- High Blood Pressure
Diabetes

SUGAR FREE

- Dye Free
Gluten Free
Alcohol Free

Alivia la tos Descongestiona el Pecho

SEGURO para los que padecen de:

- Presión alta
Diabetes

SIN AZÚCAR

- Sin Colorantes
Sin Gluten
Sin Alcohol

4 FL. OZ. (120 mL)

Español

English

4 FL. OZ. (120 mL)

k0916



Distributed by/ Distribuido por

KRAMER CONSUMER HEALTHCARE

A division of Warner-Lambert Co., Inc.

www.safetussin.com

www.kramerconsumerhealthcare.com

Coral Gables, FL 33134

1-800-824-4394

Safetussin® DM
DAY TIME COUGH RELIEF

COUGH SUPPRESSANT/ EXPECTORANT

High Blood Pressure
 Diabetes

4 FL. OZ. (120 mL)

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A division of Kramer Laboratories

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 www.safetussin.com

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Drug Facts (continued)

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 any 24-hour period

age	dose
adults and children 12 years and over	2 teaspoons every 4 hours
children under 12 years	do not use

Other information: • Protect from excessive heat and freezing. Store at 15° - 30° C (59° - 86° F)
 • Phenylethanolic: each teaspoon contains phenylethanolic 4.2 mg
Save package for complete information
Tamper evident: Do not use if imprinted seal on cap is broken, torn or missing

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Coral Gables, FL 33134
 www.kramerlabs.com
 www.safetussin.com

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Safetussin

DM DAY TIME COUGH RELIEF
COUGH SUPPRESSANT/ EXPECTORANT

High Blood Pressure

Diabetes

4 FL. OZ. (120mL)

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SAFETUSSIN DM

dextromethorpan guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55505-111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Aspartame (UNII: Z0H242BBR1)	
BENZOIC ACID (UNII: 8SKN0B0MM)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	
methylparaben (UNII: A2I8C7HI9T)	
MINT (UNII: FV98Z8GTP)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
Menthol (UNII: L7T10EIP3A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-111-33	1 in 1 CARTON	02/10/2017	
1		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/29/2010	

Labeler - Kramer Laboratories (122720675)**Establishment**

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals		001207208	manufacture(55505-111)

