

**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.*

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**Drug Facts**

<b>Active ingredients (in each 5ml tsp)</b>	<b>Purpose</b>
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
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**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**

**Safetus in DM**  
**NON-DROWSY**  
**DAY TIME**  
**COUGH RELIEF**

*Cough Suppressant / Expectorant*

Specially formulated for adults with

High Blood Pressure  
Diabetes

Relieves Cough  
Loosens Mucus

**No Sugar**  
**No Dyes**  
**No Gluten**  
**No Alcohol**

4 FL. OZ (118 ml.)

**Safetus in DM**

**ALIVIA LA TOS**  
**DURANTE EL DIA**

*Antitusivo / Expectorante*

SEGURO para los que padecen de

Presión alta  
Diabetes

Alivia la tos  
Descongestiona  
el pecho

**SIN AZÚCAR**  
**Sin** Colorantes  
**Sin** Gluten  
**Sin** Alcohol

4 FL. OZ (118 ml.)

**NON-DROWSY**  
**COUGH RELIEF**  
TO HELP YOU GET  
THROUGH THE DAY

**Pharmacist Recommended**

Developed by a pharmacist who recognized the need for simple, safe cough relief for adults afflicted with high blood pressure, diabetes or the common cold.

Specially-formulated **Safetussin**<sup>®</sup> is free of alcohol, sugar, dyes, decongestants and other ingredients that are unnecessary for safe, adult-strength cough treatment. Pure and simple.

**Questions? Comments?**  
**Call 1-800-824-4894 • [safetussin.com](http://safetussin.com)**

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K0519

DM DAY TIME COUGH RELIEF  
NON-DROWSY

Safe tussin.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL ON BOTTLE IS BROKEN OR MISSING.

**Drug Facts**

**Active ingredients**  
(in each 5mL teaspoon) **Purpose**  
Dextromethorphan HBr USP 10mg, Cough Suppressant  
Guaifenesin USP 100mg, Expectorant

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• temporarily relieves cough due to minor throat and bronchial irritation  
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age	dose
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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

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

Safe tussin.

DM

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DAY TIME  
COUGH RELIEF  
Cough Suppressant / Expectorant

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TO HELP YOU GET  
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NON-DROWSY  
DAY TIME  
COUGH RELIEF  
Cough Suppressant / Expectorant

Specially formulated for adults with

High Blood Pressure

Diabetes

Relieves Cough  
Loosens Mucus

✓ No Sugar ✓ No Gluten  
✓ No Dyes ✓ No Alcohol

4.0 FL OZ (118mL)

Safe tussin.

DM

ALIVIA LA TOS  
DURANTE  
EL DIA  
Antitusivo / Expectorante

Seguro para los que padecen de

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Diabetes

Alivia la tos  
Descongestiona  
el pecho

✓ Sin Azúcar ✓ Sin Gluten  
✓ Sin Colorantes ✓ Sin Alcohol

4.0 FL OZ (118mL)

K0319



**Safetussin® DM**  
**NON-DROWSY**  
**DAY TIME**  
**COUGH RELIEF**

*COUGH SUPPRESSANT/EXPECTORANT*

Specially formulated for adults with

High Blood Pressure  
 Diabetes

Relieves Cough  
 Loosens Mucus

4 FL. OZ. (118 mL)

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**Safetussin® DM**  
**NON-DROWSY**  
**DAY TIME**  
**COUGH RELIEF**  
*Cough Suppressant / Expectorant*

**DM** **NON-DROWSY DAY TIME COUGH RELIEF**  
*Cough Suppressant / Expectorant*

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 Loosens Mucus

4.0 FL OZ (118mL)

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**SAFETUSSIN DM**  
 dextromethorpan guaifenesin liquid

**Product Information**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>Aspartame</b> (UNII: Z0H242BBR1)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>MINT</b> (UNII: FV98Z8GITP)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>Menthol</b> (UNII: L7T10EIP3A)	

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-111-33	1 in 1 CARTON	02/10/2017	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**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 final	part341	11/29/2010	

**Labeler** - Kramer Laboratories (122720675)

**Establishment**

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

Revised: 10/2019

Kramer Laboratories