

**DEXTROMETHORPHAN HBR AND GUAIFENESIN ORAL SOLUTION-**  
**dextromethorphan hbr and guaifenesin oral solution liquid**  
**KESIN PHARMA CORPORATION**

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**Dextromethorphan HBr and Guaifenesin Oral Solution**

**Dextromethorphan HBr and Guaifenesin Oral Solution 5 and 10 mL**

*Disclaimer: Most OTC drugs are not reviewed and approved by the FDA, however, they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

**DM Guaifenesin**  
**Non-Narcotic, Sugar, Dye and Alcohol Free**  
**Cough Suppressant/Expectorant**

**DESCRIPTION**

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Each 5 mL (1 teaspoonful) contains:  
Dextromethorphan Hydrobromide 10 mg  
Guaifenesin 100 mg  
Each 10 mL (2 teaspoonfuls) contains:  
Dextromethorphan Hydrobromide 20 mg  
Guaifenesin 200 mg

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**Inactive Ingredients**

*Inactive Ingredients:* citric acid, grape flavor, methylparaben, monoammonium glycyrrhizate, potassium citrate, propylene glycol, propylparaban, purified water, sorbitol, sucralose.

**USES**

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

**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

### 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.
- you are hypersensitive to any of the ingredients.

### If pregnant or breast-feeding

**If pregnant or breast-feeding**, ask a health professional before use.

### Keep out of reach of children.

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

**Professional Note:** Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA)

## DIRECTIONS

### DIRECTIONS

Follow dosage table below or use as directed by a physician

- Do not take more than 6 doses in any 24-hour period

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#### Age

adults and children 12 years and over  
children 6 to under 12 years of age  
children 2 to under 6 years of age  
children under 2 years

#### Dose

10mL (2 teaspoonful) every 4 hours  
5mL (1 teaspoonful) every 4 hours  
2.5mL (1/2 teaspoonful) every 4 hours  
consult a doctor

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## HOW SUPPLIED

Dextromethorphan hydrobromide and Guaifenesin is a clear, grape flavor solution supplied in the following oral dosage forms:

5 mL unit dose cup:

NDC 81033-103-05

Case containing 100 units dose cups of 5 mL:  
NDC 81033-103-50

10 mL unit dose cups:  
NDC 81033-103-10

Case containing 100 unit dose cups of 10 mL:  
NDC 81033-103-51

## **STORAGE**

Store at controlled temperature 15°C to 30°C (59°F to 86°F) [See USP]. Protect from light.

## **QUESTIONS OR COMMENTS**

### **QUESTIONS OR COMMENTS**

Call 1-833-537-4679

#### **Packaged by:**

**Kesin Pharma**

Oldsmar, FL 34677

**Effective** 10/2024

**Revision** 03



**PRINCIPAL DISPLAY PANEL - 5 mL Unit Dose Cup Label**

**NDC 81033-103-05**

**Dextromethorphan HBr and Guaifenesin Oral Solution**

**Delivers 10mg/100mg per 5mL**

**FOR INSTITUTIONAL USE ONLY**

**Store at 59°F to 86°F (15°C to 30°C)**

**Delivers 5mL**

NDC 81033-103-05

**Dextromethorphan HBr &  
Guaifenesin Oral Solution**

10mg/100mg per 5mL

Cough Suppressant  
/ Expectorant

Sugar, Alcohol, Dye Free



(01)00381033103051

Store at 68°F to 77°F

See Insert

For Institutional Use Only

Pkg by:

Kesin Pharma  
Oldsmar, FL 34677  
K2410213  
04/30/2026

**PRINCIPAL DISPLAY PANEL - 10 mL Unit Dose Cup Label**

**NDC 81033-103-10**

**Dextromethorphan HBr and Guaifenesin Oral Solution**

**Delivers 20mg/200mg per 10mL**

**FOR INSTITUTIONAL USE ONLY**

**Store at 59°F to 86°F (15°C to 30°C)**

**Delivers 10mL**

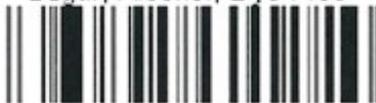
NDC 81033-103-10

**Dextromethorphan HBr &  
Guaifenesin Oral Solution**

20mg/200mg per 10mL

Cough Suppressant  
/ Expectorant

Sugar, Alcohol, Dye Free



(01)00381033103105

Store at 68°F to 77°F

See Insert

For Institutional Use Only

Pkg by:

Kesin Pharma  
Oldsmar, FL 34677  
K2410214 04/30/2026



**DEXTROMETHORPHAN HBR AND GUAIFENESIN ORAL SOLUTION**

dextromethorphan hbr and guaifenesin oral solution liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81033-103(NDC:84447-102)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-103-50	100 in 1 CASE	12/02/2024	
1	NDC:81033-103-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-103-51	100 in 1 CASE	12/02/2024	
2	NDC:81033-103-10	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/02/2024	

**Labeler** - KESIN PHARMA CORPORATION (117447816)

### Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma Corporation		117447816	repack(81033-103)

### Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma Corporation		119132647	repack(81033-103)

Revised: 1/2025

KESIN PHARMA CORPORATION