

**GUAIFENESIN- guaifenesin liquid**  
**KESIN PHARMA CORPORATION**

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**Guaifenesin Oral Solution, USP**

**Guaifenesin Solution 5mL**

***Expectorant***

Sugar Free / Dye Free / Alcohol Free

**Description**

Each 5mL (1 teaspoonful) contains: Guaifenesin 100mg

**Inactive Ingredients**

Mixture of Guaifenesin with GRAS material additions including Citric Acid, Grape Flavor Methylparaben, Monoammonium Glycyrrhizate, Potassium Citrate, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Sucralose

**Uses**

Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

**Warnings**

**Ask a doctor before us 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 and ask a doctor if**

- cough lasts mor 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,** 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.

**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

Follow dosage below or use as directed by a physician.

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

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<b>Age</b>	<b>Dose</b>
Adults and children 12 years and over	10 to 20mL (2 to 4 teaspoonfuls) every 4 hours
Children 6 years to under 12 years	5 to 10mL (1 to 2 teaspoonfuls) every 4 hours
Children 2 to under 6 years of age	2.5 to 5mL (1/2 to 1 teaspoonful) every 4 hours
Children under 2 years of age	Consult a physician

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## How Supplied:

Guaifenesin Oral Solution is a clear, colorless solution with a grape flavor, free of visible foreign matter supplied in the following oral dosage forms:

NDC 81033-102-05: 5mL unit dose cup

NDC 81033-102-51: Case containing 100 unit dose cups of 5 mL packaged in 2 cartons of 50 unit dose cups each

NDC 81033-102-10: 10mL unit dose cup

NDC 81033-102-52: Case containing 100 unit dose cups of 10 mL packaged in 2 cartons of 50 unit dose cups each

NDC 81033-102-15: 15 mL unit dose cup

NDC 81033-102-53: Case containing 100 unit dose cups of 15 mL packaged in 2 cartons of 50 unit dose cups each

## STORAGE

Keep tightly closed. Store at controlled room temperature, 20°C to 25°C (68°F to 77°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: 09/2024

Rev. 03

**5 mL Unit Dose Cup Case Label**

NDC 81033-102-51

**Guaifenesin Oral Solution, USP100 mg/5 mL**

Delivers 5 mL

Case = 100 UD Cups (Do Not Break Case)

Store at 68°F to 77°F (20°C to 25°C)

QTY 1

NDC: 81033-102-51

Product Name: **Guaifenesin Oral Solution, USP 100 mg/5 mL**

Delivers: 5 mL Case = 100 UD Cups (Do Not Break Case)

Storage: 68°F to 77°F (20°C to 25°C)

EXP: XX-XXX-XXXX LOT: KXXXXXXXX QTY: 1



(17) XXXXXX (10) KXXXXXXXX (30) 1



(01) 20381033102515



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Kesin Pharma Corporation - Oldsmar, FL

Internal Use Only R.01



KXXXXXXXX

**10 mL Unit Dose Cup Case Label**

NDC 81033-102-52

**Guaifenesin Oral Solution, USP 200 mg/10 mL**

Delivers 10 mL

Case = 100 UD Cups (Do Not Break Case)

Store at 68°F to 77°F (20°C to 25°C)

QTY 1

NDC: 81033-102-52

Product Name: **Guaifenesin Oral Solution, USP 200 mg/10 mL**

Delivers: 10 mL Case = 100 UD Cups (Do Not Break Case)

Storage: 68°F to 77°F (20°C to 25°C)

EXP: XX-XXX-XXXX LOT: KXXXXXXXX QTY: 1



(17) XXXXXX (10) KXXXXXXXX (30) 1



(01) 20381033102522



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KXXXXXXXX

## 15 mL Unit Dose Cup Case Label

NDC 81033-102-53

**Guaifenesin Oral Solution, USP 300 mg/15 mL**

Delivers 15 mL

Case = 100 UD Cups (Do Not Break Case)

QTY 1

NDC: 81033-102-53

Product Name: **Guaifenesin Oral Solution, USP 300 mg/15 mL**

Delivers : 15 mL Case = 100 UD Cups (Do Not Break Case)

Storage: 68°F to 77°F (20°C to 25°C)

EXP: XX-XXX-XXXX LOT: KXXXXXXXX QTY: 1



(17) XXXXXX (10) KXXXXXXXX (30) 1



(01) 20381033102539



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Internal Use Only R.01



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## GUAIFENESIN

guaifenesin liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81033-102
<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

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>POTASSIUM CITRATE ANHYDROUS</b> (UNII: 86R1NVR0HW)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## 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:81033-102-51	50 in 1 CARTON	11/20/2023	
1	NDC:81033-102-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-102-52	50 in 1 CARTON	11/20/2023	
2	NDC:81033-102-10	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	11/20/2023	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma		117447816	pack(81033-102) , label(81033-102)

## Establishment

Name	Address	ID/FEI	Business Operations
Belleview Biosciences		131968803	manufacture(81033-102) , label(81033-102) , analysis(81033-102)

Revised: 3/2025

KESIN PHARMA CORPORATION