

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

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**Guaifenesin Oral Solution**

**Guaifenesin**

**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.

**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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| Age                                   | Dose  |
|---------------------------------------|---|
| 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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**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 Guaifenesin 100mg/5mL (Unit Dose Cup 5mL)**  
**NDC 81033-102-10 Guaifenesin 200mg/10mL (Unit Dose Cup 10mL)**

**STORAGE**

**Keep tightly closed. Store at 15-30°C (59-86°F)**

**QUESTIONS OR COMMENTS**

**Call 1-833-537-4679**

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

**NDC 81033-102-51**

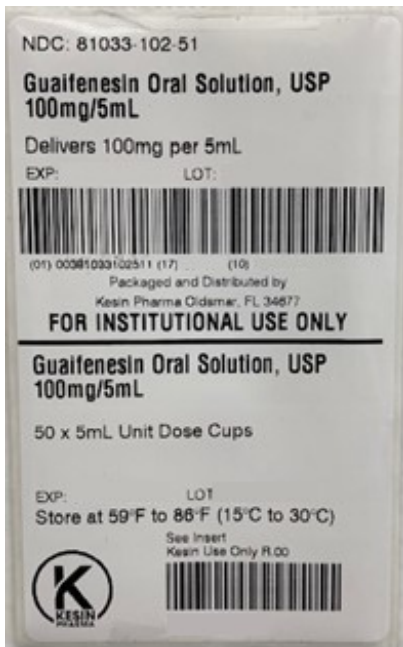
**Guaifenesin Oral Solution, USP**

**Delivers 100mg per 5mL**

**FOR INSTITUTIONAL USE ONLY**

**50 X 5 mL Unit Dose Cups**

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



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

**NDC 81033-102-52**

**Guaifenesin Oral Solution, USP**

**Delivers 200mg per 10mL**

**FOR INSTITUTIONAL USE ONLY**

**50 X 10 mL Unit Dose Cups**

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



**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    |
|----------------------|---------|-----------|------------------------|
| Wittman Pharma, Inc. |         | 830980947 | manufacture(81033-102) |

Revised: 3/2024

KESIN PHARMA CORPORATION