

**GUAIFENESIN- guaifenesin solution**  
**A-S Medication Solutions**

*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**

**Active ingredient**

Each 5 mL (1 teaspoonful) contains:

Guaifenesin ..... 100 mg

**Inactive ingredients**

Acesulfame K, artificial cherry & vanilla flavor, aspartame, hypromellose, menthol, methylparaben, potassium sorbate, purified water. Citric acid may be used to adjust pH.

**Purpose**

Expectorant

**Uses**

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

**Warnings**

**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,**

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

age	dose
adults and children 12 years and over	10 to 20 mL (2 to 4 teaspoonfuls) every 4 hours
children 6 years to under 12 years	5 to 10 mL (1 to 2 teaspoonfuls) every 4 hours
children 2 to under 6 years of age	2.5 to 5 mL (1/2 to 1 teaspoonful) every 4 hours
children under 2 years of age	ask a doctor

## How Supplied:

Guaifenesin Oral Solution is a clear viscous liquid with a slight cherry odor supplied in the following oral dosage forms: 5 mL unit dose, 10 mL unit dose, 15 mL unit dose in trays of 10 and 4 fl. oz. (118 mL) bottle

Phenylketonurics: contains phenylalanine 8.4 mg per teaspoonful (5 mL)

## STORAGE

Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F). [See USP] Protect from light.

## Questions or comments?

Call **1-800-262-9010**.

## Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Rev.063:01 4/13

MG #29850

## HOW SUPPLIED

Product: 50090-4856

NDC: 50090-4856-0 10 mL in a CUP, UNIT-DOSE / 10 in a TRAY

# GUAIFENESIN SOLUTION



## GUAIFENESIN

guaifenesin solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-4856(NDC:50383-063)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

### Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
CHERRY (artificial cherry flavor) , VANILLA (artificial vanilla flavor)	
<b>Contains</b>	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4856-0	10 in 1 TRAY	01/21/2020	
1		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 final	part341	03/07/2012	

**Labeler** - A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4856)

Revised: 3/2021

A-S Medication Solutions