

**GUAIFENESIN- guaifenesin solution**  
**Hi-Tech Pharmcal Co., Inc.**

*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.063:00 10/10

MG #29850

### **Package/Label Principal Display Panel**



**Delivers 15 mL**  
**NDC 50383-063-15**  
**GUAIFENESIN ORAL SOLUTION**  
**300 mg/15 mL**  
**Sugar Free/Alcohol Free**  
**EXPECTORANT**  
**SEE INSERT**  
**FOR INSTITUTIONAL USE ONLY**  
 Hi-Tech Pharmacal Co., Inc.  
 Amityville, NY 11701  
 Rev. 063:00 10/10

**GUAIFENESIN**

guaifenesin solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	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 (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50383-063-06	4 in 1 CASE		
1	NDC:50383-063-05	10 in 1 TRAY		
1		5 mL in 1 CUP, UNIT-DOSE		
2	NDC:50383-063-07	10 in 1 CASE		
2		10 in 1 TRAY		
2		5 mL in 1 CUP, UNIT-DOSE		
3	NDC:50383-063-11	4 in 1 CASE		
3	NDC:50383-063-10	10 in 1 TRAY		
3		10 mL in 1 CUP, UNIT-DOSE		
4	NDC:50383-063-12	10 in 1 CASE		
4		10 in 1 TRAY		
4		10 mL in 1 CUP, UNIT-DOSE		
5	NDC:50383-063-17	4 in 1 CASE		
5	NDC:50383-063-15	10 in 1 TRAY		
5		15 mL in 1 CUP, UNIT-DOSE		
6	NDC:50383-063-18	10 in 1 CASE		
6		10 in 1 TRAY		
6		15 mL in 1 CUP, UNIT-DOSE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/07/2012	

**Labeler** - Hi-Tech Pharmacal Co., Inc. (101196749)

### Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Pharmacal Co., Inc.		101196749	MANUFACTURE(50383-063)

Revised: 3/2013

Hi-Tech Pharmacal Co., Inc.