# DIABETIC TUSSIN EXPECTORANT- guaifenes in liquid Health Care Products

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 (in each 5 mL)

Guaifenesin 100 mg

### Purpose

Expectorant

#### Uses

 helps loosen phlegm (mucus) and thin bronchial secretions to rid bronchial passageways of bothersome mucus

## Warnings

## Ask a doctor before use if you have:

- a cough that occurs with too much phlegm (mucus)
- a persistent or chronic cough 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 occurs with fever, rash, or headache that lasts

These could be signs of a serious condition.

#### 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**

- take every 4 hours
- do not exceed 6 doses in 24 hours

adults & children 12 years and over	10 mL - 20 mL (2 - 4 teaspoonfuls)
children 6 years to under 12 years	5 mL - 10 mL (1 - 2 teaspoonfuls)
children 2 years to under 6 years	2.5 mL - 5 mL (½ - 1 teaspoonful)
children under 2 years	ask a doctor

#### Other information

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

- store at room temperature 20-25°C (68-77°F).
- keep tightly closed.

## **Inactive ingredients**

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

#### Questions or comments?

Call **1-800-899-3116**, Mon-Thurs 9:00 am - 5:00 pm EST, Fri 9:00 am - 2:30 pm EST. Serious side effects associated with use of this product may be reported to this number.

Rev #063:05 10/11

## Package/Label Principal Display Panel



NDC 61787-063-04

Diabetic Tussin®

Guaifenesin 100 mg/5 mL

**Expectorant** 

Loosens & Relieves Chest Congestion

Thins & Loosens Mucus
Liquid
No Sodium, Sorbitol, Fructose & Dyes
SUGAR & ALCOHOL FREE!
SAFE FOR DIABETICS

4 FL OZ (118 mL)

## DIABETIC TUSSIN EXPECTORANT

guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:61787-063
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (GUAIFENESIN)	GUAIFENESIN	100 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ACESULFAME POTASSIUM			
ASPARTAME			
HYPROMELLOSES			
MENTHO L			
METHYLPARABEN			
POTASSIUM SORBATE			
WATER			
ANHYDROUS CITRIC ACID			

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:61787-063-04	1 in 1 BOX		
1	118 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 1/0 1/19 9 6	

## Labeler - Health Care Products (101196749)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Hi-Tech Pharmacal Co., Inc.		10 119 6 749	MANUFACTURE(61787-063)	

Revised: 9/2012 Health Care Products