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.

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)

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)

Product Info	ormation						
Product Type			HUMAN OTC DRUG	Item Co	de (Source)	NDO	C:61787-063
Route of Admi	nistration		ORAL				
Active Ingre	dient/Ac	tive Moi	ety				
		Ingre	dient Name		Basis of S	Strength	Strength
GUAIFENESIN (UNII: 495W		UAIFENESIN - UNII:495W745	51VQ)	GUAIFENESI	N	100 mg in 5 mL
Inactive Ing	redients		Ingredient Name				Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)							o trong tr
ASPARTAME (U							
HYPRO MELLO	SE, UNSPE	CIFIED (UN	III: 3NXW29V3WO)				
MENTHOL, UNS	SPECIFIED	FORM (UN	II: L7T10EIP3A)				
METHYLPARA	BEN (UNII:	A218C7H19T)				
PO TASSIUM SC			JZZ4)				
WATER (UNII: 0							
ANHYDRO US C	ITRIC ACI	D (UNII: XF ²	17D3PSL)				
Product Cha	ractaria	tics					
	racteris	ucs				Sco	ro
Shape						Size	
-	-						rint Code
Contains	(-)	Imp	
contains							
Packaging							
# Item Co	de		Package Description		Marketing Start	Date Ma	arketing End Da
1 NDC:61787-0					0 1/0 1/19 9 6		
1	110	I . 1 DO	TLE; Type 0: Not a Combina	tion Droduct			

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.		101196749	MANUFACTURE(61787-063)			

Revised: 12/2019

Health Care Products