

DIABETIC TUSSIN EXPECTORANT - guaifenesin liquid

Central Texas Community Health Centers

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)
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

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Label

City of Austin Dept of Health

GUAIFENESIN

118ml

Date:

Name:

Dr.

TAKE AS DIRECTED.

1/1/01

123456

GUAIFENESIN 118ml NDC 76413-335-01

Batch: 123456

Lot: 123456

Exp: 1/1/01

AKORN

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

City of Austin Dept of Health

GUAIFENESIN
118ml

Date:

Name:

Dr.

TAKE AS DIRECTED.

TOMAR COMO INDICADO.

1/1/01

123456

GUAIFENESIN 118ml NDC 76413-335-01

Batch: 123458 Lot: 123458

Exp: 1/1/01

AKORN

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

DIABETIC TUSSIN EXPECTORANT

guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-335(NDC:61787-063)
Route of Administration	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, UNSPECIFIED (UNII: 3NXW29V3WO)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		Score	
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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:76413-335-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/1996	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	01/01/1996		

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-335) , RELABEL(76413-335)

Revised: 8/2017

Central Texas Community Health Centers