

# **GUAIFENESIN 100MG/5ML- guaifenesin solution**

## **Bellevue Biosciences**

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### **Guaifenesin Oral Solution 100mg/5mL**

#### **Dosage & Admin**

Directions:

- do not take more than 6 doses in any 24-hour period.

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AGE	DOSE
Adults & Children 12 years and over	2-4 teaspoonfuls every 4 hours
Children 6 years to under 12 years	1-2 teaspoonfuls every 4 hours
Children 2 to under 6 years	1/2 - 1 teaspoonfuls every 4 hours
Children Under 2 years	Ask a Doctor

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#### **Warnings**

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.

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.

Inactive Ingredients: Citric Acid, Flavor, Methylparaben, Monoammonium Glycyrrhizinate, Potassium Citrate, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Sucralose

Uses:

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Purpose: Expectorant

Active Ingredient (in each 5 mL tsp)

Guaifenesin 100 mg

**NDC 84447-101-01**  
**Guaifenesin Oral Solution**  
**Guaifenesin 100mg/5ml**

**Bulk Label**

**Lot:**  
**Mfg:**

**BULK SHIPMENT**  
**PLEASE HANDLE CAREFULLY**

**Contains:**  
100mg Guaifenesin per 5 ml; Inactive Ingredients: Citric Acid, Flavor, Methylparaben, Monoammonium Glycyrrhizinate, Potassium Citrate, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Sucralose

**\*\*Sugar, Alcohol, Gluten and Dye Free\*\***

**CAUTION:**  
**FOR REPACKAGING ONLY**  
**Store at controlled room temperature 15°-30°C (59°- 86°F)**

**BELLEVIEW**  
**BIOSCIENCE**  
Manufactured by:  
Bellevue Biosciences LLC.  
Brooksville, FL 34604

Gross wt: _____
Tare wt: _____
Net wt: _____
Drum: _____ of _____

**GUAIFENESIN 100MG/5ML**

guaifenesin solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84447-101
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84447-101-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2024	
2	NDC:84447-101-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2024	
3	NDC:84447-101-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2024	
4	NDC:84447-101-01	200000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2024	

Drug Facts	
<b>Active Ingredient (in each 5 mL tsp)</b> Guaifenesin 100 mg	<b>Purpose</b> Expectorant
<b>Uses:</b> ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive	
<b>Warnings:</b> <b>Ask a doctor before use if you have</b> ■ 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 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.	
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.	
<b>Directions:</b> ■ do not take more than 6 doses in any 24-hour period.	
Age	Dose
adults and children 12 years and over	2-4 teaspoonfuls every 4 hours

MADE IN THE USA

NDC 83335-101-16

## CuraTUSSIN

### EXPECTORANT

GUAIFENESIN 100 mg / 5 mL

**LOOSENS AND RELIEVES CHEST CONGESTION**

Compare to the active ingredient in \*Robitussin\*

✓ SUGAR FREE    ✓ ALCOHOL FREE  
 ✓ DYE FREE      ✓ GLUTEN FREE

Net Content: 16 fl oz (473 mL)  
Grape Flavor


**Wittman  
Pharma**

Drug Facts (continued)	
<b>Directions: (continued)</b> ■ do not take more than 6 doses in any 24-hour period.	
Age	Dose
children 6 years to under 12 years	1-2 teaspoonfuls every 4 hours
children 2 years to under 6 years	½-1 teaspoonfuls every 4 hours
under 2 years	ask a doctor
<b>Other information</b> ■ store at 15°-30°C (59°-86°F) ■ tamper evident, do not use if imprinted safety seal under cap is broken or missing	
<b>Inactive Ingredients:</b> Citric Acid, Flavor, Methylparaben, Monoammonium Glycyrhizinate, Potassium Citrate, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Sucralose	
<b>Questions?</b> Call 1-352-549-9917 M-F 9am - 5pm EST Manufactured for: Wittman Pharma, Inc. Brooksville, FL 34604	
*Robitussin® is a registered trademark of Wyeth Consumer Healthcare. Rev. 1/2024	
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug	M012	10/01/2024	
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**Labeler** - Belleview Biosciences (131968803)

**Registrant** - Belleview Biosciences (131968803)

**Establishment**

Name	Address	ID/FEI	Business Operations
Belleview Biosciences		131968803	manufacture(84447-101) , label(84447-101) , analysis(84447-101)

Revised: 11/2024

Belleview Biosciences