

GUAIFENESIN 100MG/5ML- guaifenesin solution

Bellevue Biosciences

Guaifenesin Oral Solution 100mg/5mL

Dosage & Admin

Directions:

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

| 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 |

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

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:84447-101 |
| 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 |
|---|----------|
| 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 | |

| Drug Facts | |
|---|--------------------------------|
| Active Ingredient (in each 5 mL tsp) | Purpose |
| Guaifenesin 100 mg | Expectorant |
| Uses: | |
| <ul style="list-style-type: none"> helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive | |
| Warnings: | |
| <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> cough that occurs with too much phlegm (mucus) cough that lasts or is chronic, such as occurs with smoking, asthma, chronic bronchitis, or emphysema | |
| <p>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.</p> | |
| <p>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.</p> | |
| Directions: | |
| 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 |

NDC 83335-101-16

MADE IN THE USA

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



| Drug Facts (continued) | |
|---|--------------------------------|
| Directions: (continued) | |
| 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 |
| Other information | |
| <ul style="list-style-type: none"> store at 15°-30°C (59°-86°F) tamper evident, do not use if imprinted safety seal under cap is broken or missing | |
| Inactive Ingredients: Citric Acid, Flavor, Methylparaben, Monoammonium Glycyrhizinate, Potassium Citrate, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Sucralose | |
| Questions? 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 | |
|  N 3 83335 10116 2 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 10/01/2024 | |

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: 7/2024

Belleview Biosciences