

GADAVYT COUGH - guaifenesin liquid
Gadal Laboratories Inc

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 tsp.) | Purpose |
|--|----------------|
| Guaifenesin 100mg | Expectorant |

USES

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

Warnings

Ask a doctor before use if

- you have cough that lasts or a chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema.
- cough occurs with too much phlegm (mucus)

Stop use and ask a doctor if

- cough lasts for more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

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

If pregnant or breast-feeding, ask a health professional before use.

Directions

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

| | |
|---------------------------------------|--|
| adults and children 12 years and over | 2-4 TSP every 4 hours or as directed by doctor |
| children under 12 years | do not use |

Other information

store at room temperature 15 - 30 degrees C (59 - 86 degrees F)

TAMPER-EVIDENT: Do not use if seal under cap is torn, broken or missing.

Inactive Ingredients

Citric acid, menthol, methylparaben, propylparaben, glycerin, sucralose, sodium citrate, FD and C Red No. 40, caramel color, cherry flavor, natrosol, purified water.

GADAL Laboratories, Inc.

Miami, Fl 33186

www.gadallaboratories.com

NDC 53113-550-04

Drug Facts

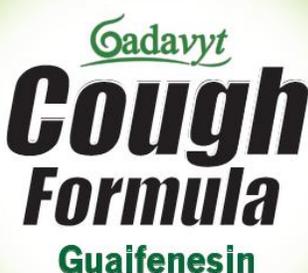
Active ingredient (in each 5ml tsp.) **Purpose**
Guaifenesin USP 100mg.....Expectorant

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

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**Sugar Free
Alcohol Free**

Adult

• **Expectorant**

Cherry Flavor
4 FL OZ (118 ml)

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| | | |
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MANUFACTURED BY:
GADALL Laboratories, Inc.
Miami, FL 33186
www.gadalaboratories.com

DISTRIBUTED BY:
SSS GROUP, LLC.
Miami, FL 33186

Lot- No.:
Exp. Date:



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GADAVYT COUGH

guaifenesin liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53113-550 |
| 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 |
|--|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16) | |
| WATER (UNII: 059QF0K00R) | |

Product Characteristics

| | | | |
|---------------|------------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | CHERRY (Cherry Flavor) | Imprint Code | |

Contains**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:53113-550-04 | 118 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 12/01/2012 | |

Labeler - Gadal Laboratories Inc (841305639)

Revised: 12/2012

Gadal Laboratories Inc