

CHEST CONGESTION RELIEF- guaifenesin liquid

RUGBY LABORATORIES

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.

Active ingredients

Guaifenesin 100 mg

Purpose

Expectorant

Uses

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

Warnings

Do not use if you ever had an allergic reaction to any of the ingredients in this product

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 (1-800-222-1222) right away.

Directions

- Do not take more than 6 doses in a 24 hour period
- Do not exceed recommended dose

Adults and children 12 years and over
children under 12 years

2 to 4 teaspoonfuls every 4 hours
ask a doctor

Inactive ingredients. Artificial and natural cherry flavor, citric acid, FD&C Red #40, menthol, methylparaben, propylene glycol, propylparaben water, sodium citrate, sucralose

Questions or comments? 1-800-645-2158



NDC 0536-1314-85
Compare to the active ingredient in Robitussin®*

Chest Congestion Relief

Guaifenesin Oral Solution, USP



Expectorant

Loosens and Relieves Chest Congestion

Cherry Menthol Flavor
Sugar Free
Alcohol Free

16 FL OZ (473 mL)

Drug Facts

Active ingredient (in each 5mL teaspoonful) Purpose
Guaifenesin, USP 100mg.....Expectorant

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Other information ■ **TAMPER-EVIDENT:** Do not use if foil seal over bottle opening is torn, broken, or missing ■ store at room temperature 15°- 30°C (59°-86°F) ■ protect from freezing ■ protect from light
■ Pharmacist-Preserve and dispense in a tight, light-resistant container with a child resistant cap as defined in the USP

Inactive ingredients: Artificial and natural cherry flavor, citric acid, FD&C red #40, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Questions or comments? 1-800-645-2158

*This product is not manufactured or distributed by the owner of registered trademark of Robitussin®.

Lot#

Exp. Date:

Rev.03/22 R-164 Re-order No. 371051



THIS IS A BULK CONTAINER NOT INTENDED FOR RETAIL.

Distributed by:
RUGBY® LABORATORIES
Indianapolis, IN 46268
www.rugbylaboratories.com

Code#L-67

CHEST CONGESTION RELIEF

guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1314
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sodium citrate (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1314-85	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		10/01/2020	

Labeler - RUGBY LABORATORIES (079246066)

Revised: 3/2022

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